



1 I, Phillip Bennett, declare and state as follows:

2 1. I am a partner in the law firm of Knobbe, Martens, Olson & Bear, LLP, and I  
3 am counsel of record for KFx Medical Corporation ("KFx") in this action. I submit this  
4 Declaration in Support of KFx's Motion to (a) Dismiss Defendant's Counterclaims for  
5 Inequitable Conduct in Connection with U.S. Patents 8,100,942 and 8,109,969; (b) Strike the  
6 Corresponding Affirmative Defense; and (c) Extend Time to Answer Remaining  
7 Counterclaim Allegations. The following statements are based on my personal knowledge  
8 unless otherwise indicated.

9 2. Attached hereto as Exhibit 1 is a true and correct copy of U.S. Patent No.  
10 7,585,311, the patent originally asserted in this action.

11 3. Attached hereto as Exhibit 2 is a true and correct copy of U.S. Patent No.  
12 8.100,942, one of the two continuation patents added by KFx's First Amended Complaint,  
13 which is at issue in this Motion.

14 4. Attached hereto as Exhibit 3 is a true and correct copy of U.S. Patent No.  
15 8.109,969, the other of the two continuation patents added by KFx's First Amended  
16 Complaint, which is also at issue in this Motion.

17 5. Attached hereto as Exhibit 4 is a true and correct copy of the December 1,  
18 2011 IDS submitted in the continuation application 13/245620.

19 6. Attached hereto as Exhibit 5 is a true and correct copy of the December 1,  
20 2011 IDS submitted in the continuation application 13/245622.

21 7. Attached hereto as Exhibit 6 is a true and correct copy of the Notice of  
22 Allowability issued by the Examiner in the continuation application 13/245620.

23 8. Attached hereto as Exhibit 7 is a true and correct copy of the Notice of  
24 Allowability issued by the Examiner in the continuation application 13/245622.

25 9. Attached hereto as Exhibit 8 is a true and correct copy of the List of  
26 References cited by the Examiner in the continuation application 13/245620 indicating that  
27 all references were considered except where lined through.

28 ///



**PROOF OF SERVICE**

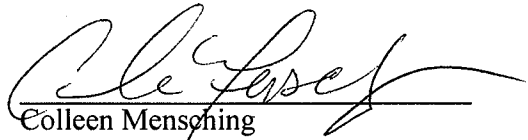
I hereby certify that on May 24, 2012, I caused the **DECLARATION OF PHILLIP BENNETT IN SUPPORT OF PLAINTIFF'S MOTION TO (A) DISMISS DEFENDANT'S COUNTERCLAIM FOR INEQUITABLE CONDUCT IN CONNECTION WITH U.S. PATENTS 8,100,942 AND 8,109,969; (B) STRIKE THE CORRESPONDING AFFIRMATIVE DEFENSE; AND (C) EXTEND TIME TO ANSWER REMAINING COUNTERCLAIM ALLEGATIONS** to be electronically filed with the Clerk of the Court using the CM/ECF system which will send electronic notification of such filing to the following person(s):

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I certify and declare under penalty of perjury under the laws of the State of California that I am employed in the office of a member of the bar of this Court at whose direction the service was made, and that the forgoing is true and correct.

Executed on May 24, 2012, at San Diego, California.

  
Colleen Mensching

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**TABLE OF EXHIBITS****Page No.**

1		
2		
3	Exhibit 1.....	1
4	Exhibit 2.....	37
5	Exhibit 3.....	72
6	Exhibit 4.....	107
7	Exhibit 5.....	117
8	Exhibit 6.....	127
9	Exhibit 7.....	131
10	Exhibit 8.....	135
11	Exhibit 9.....	143
12	Exhibit 10.....	150

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# **EXHIBIT 1**



US007585311B2

(12) **United States Patent**  
**Green et al.**

(10) **Patent No.:** **US 7,585,311 B2**  
(45) **Date of Patent:** **Sep. 8, 2009**

(54) **SYSTEM AND METHOD FOR ATTACHING  
SOFT TISSUE TO BONE**

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(73) **Assignee:** **KFx Medical Corporation**, Carlsbad,  
CA (US)

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(\*) **Notice:** Subject to any disclaimer, the term of this  
patent is extended or adjusted under 35  
U.S.C. 154(b) by 749 days.

(Continued)

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(21) **Appl. No.:** **11/143,007**

International Preliminary Report on Patentability mailed Jan. 25,  
2007 for International Application No. PCT/US2005/019454.

(22) **Filed:** **Jun. 1, 2005**

(Continued)

(65) **Prior Publication Data**

US 2006/0004364 A1 Jan. 5, 2006

*Primary Examiner*—(Jackie) Tan-Uyen T. Ho

*Assistant Examiner*—Gregory A Anderson

(74) *Attorney, Agent, or Firm*—Knobbe, Martens, Olson &  
Bear LLP

**Related U.S. Application Data**

(60) Provisional application No. 60/576,477, filed on Jun.  
2, 2004, provisional application No. 60/610,924, filed  
on Sep. 17, 2004, provisional application No. 60/634,  
174, filed on Dec. 7, 2004.

(57)

**ABSTRACT**

Disclosed herein are methods and devices for securing soft  
tissue to a rigid material such as bone. A bone anchor is  
described that comprises a base and a top such that suture  
material may be compressed between surfaces on the base  
and top to secure the suture to the anchor. Also described is an  
insert that can be used to insert the bone anchor into bone  
and move the anchor top relative to the anchor base to clamp  
suture material there between. Also described is a soft-tissue  
and bone piercing anchor and associated inserter. Methods  
are described that allow use of the bone anchors to provide  
multiple lengths of suture material to compress a large area of  
soft tissue against bone.

(51) **Int. Cl.**  
**A61B 17/04** (2006.01)

(52) **U.S. Cl.** 606/232

(58) **Field of Classification Search** 606/232,  
606/72, 75, 78, 219, 224

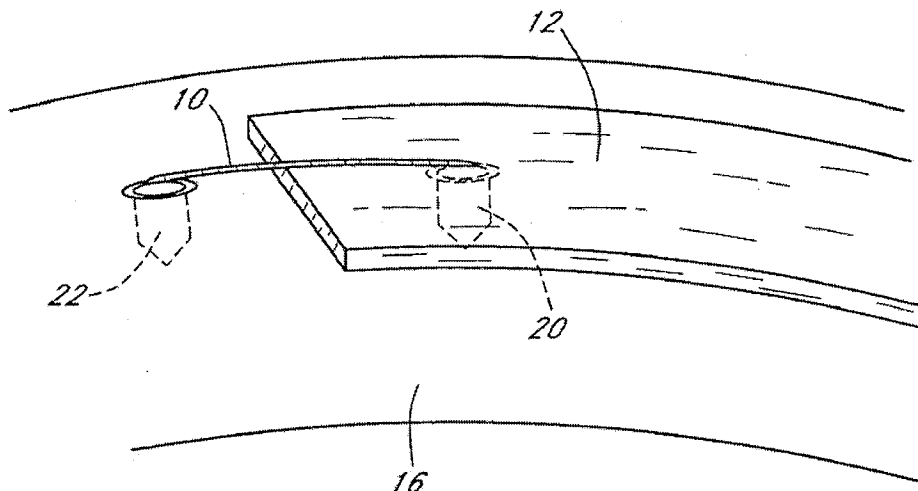
See application file for complete search history.

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**30 Claims, 24 Drawing Sheets**



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EXHIBIT 1  
PAGE 2



US 7,585,311 B2

Page 3

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U.S. Patent

Sep. 8, 2009

Sheet 1 of 24

US 7,585,311 B2

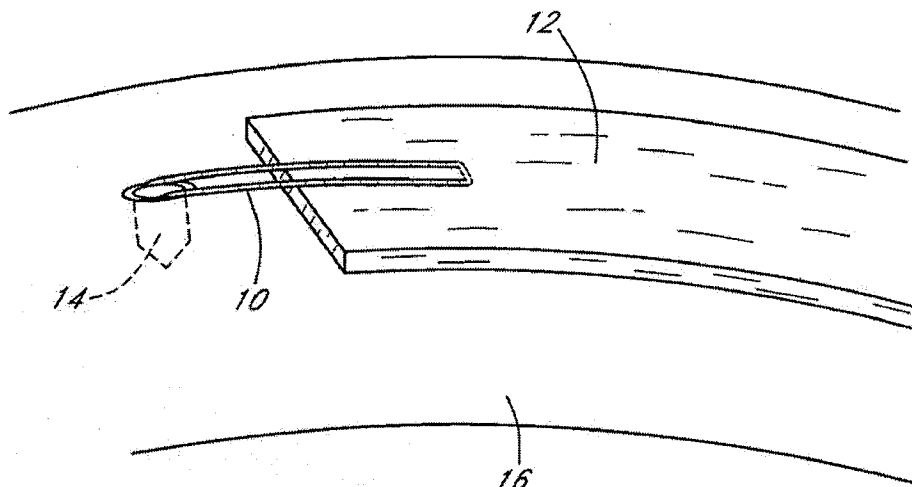


FIG. 1

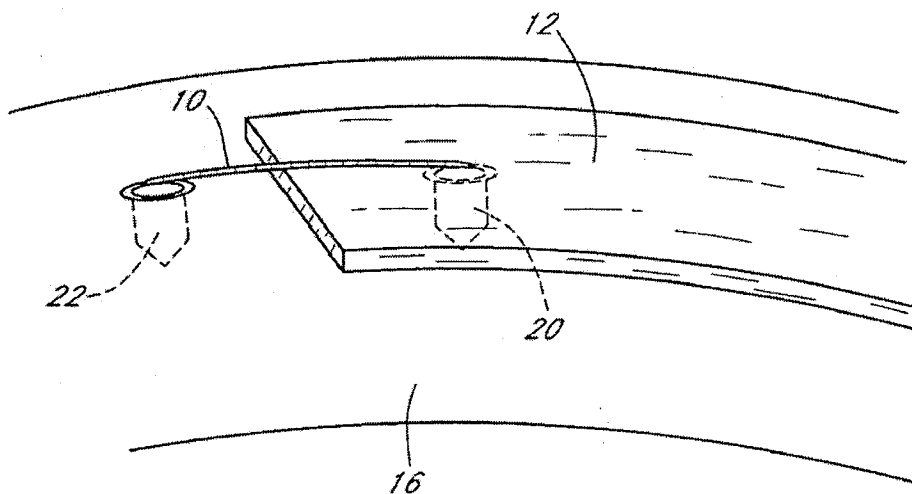


FIG. 2

U.S. Patent

Sep. 8, 2009

Sheet 2 of 24

US 7,585,311 B2

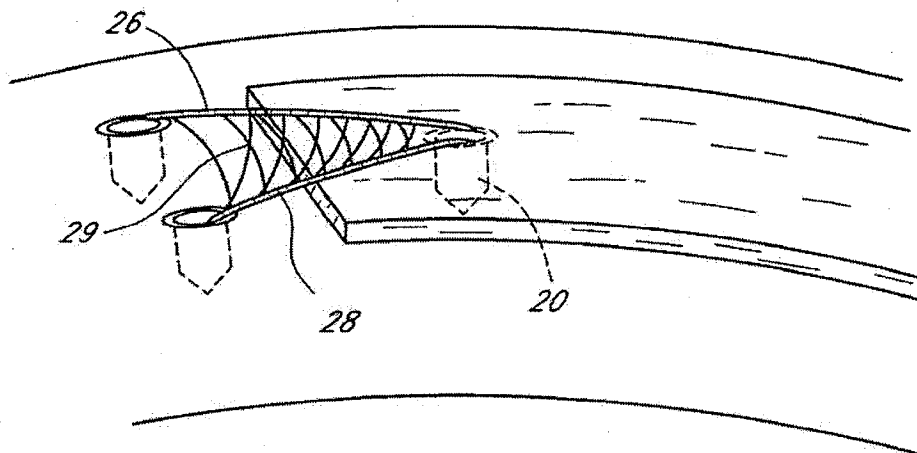


FIG. 3A

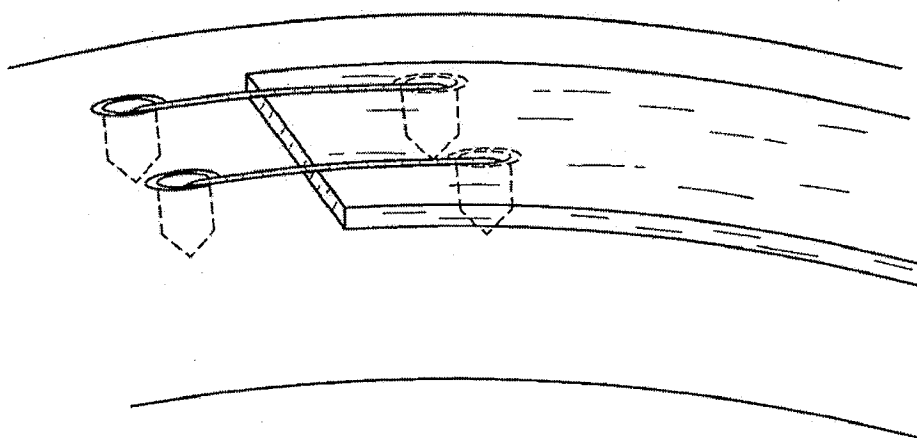


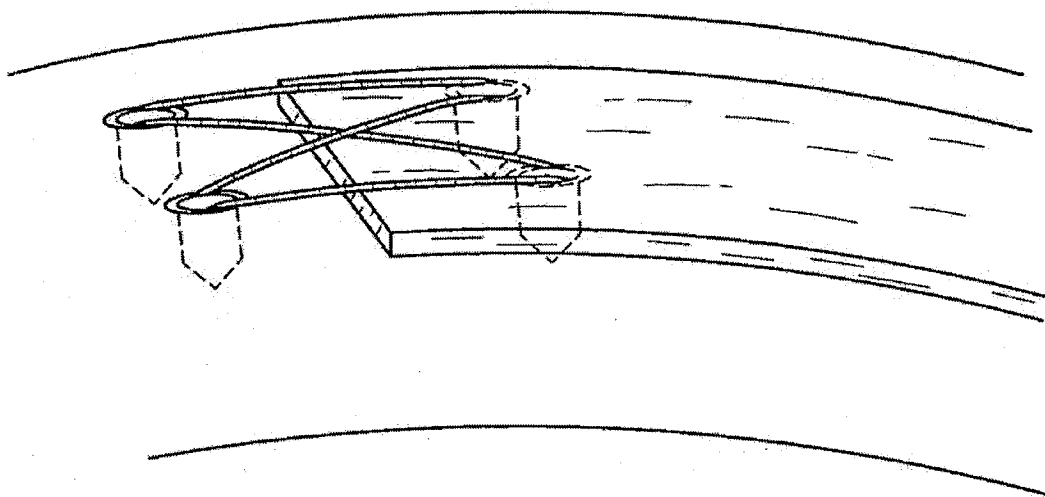
FIG. 3B

**U.S. Patent**

**Sep. 8, 2009**

**Sheet 3 of 24**

**US 7,585,311 B2**



**FIG. 3C**

U.S. Patent

Sep. 8, 2009

Sheet 4 of 24

US 7,585,311 B2

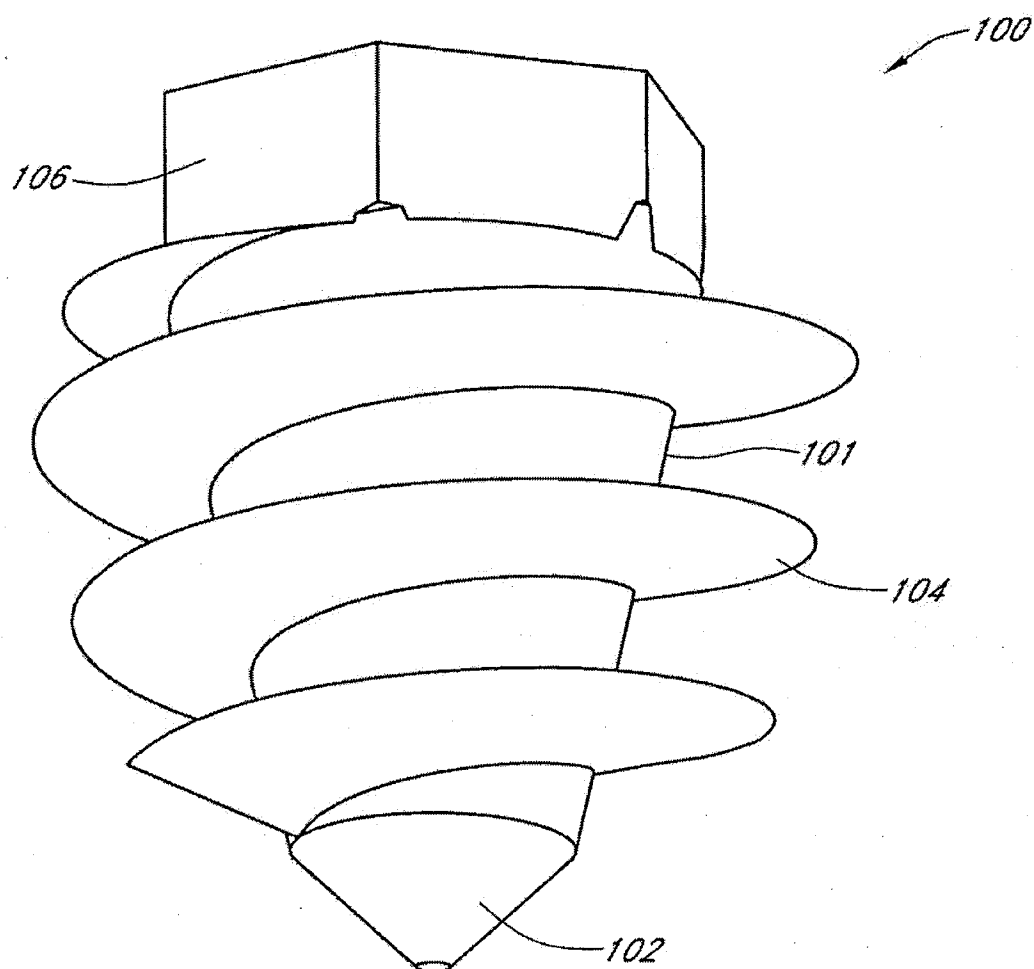


FIG. 4A

U.S. Patent

Sep. 8, 2009

Sheet 5 of 24

US 7,585,311 B2

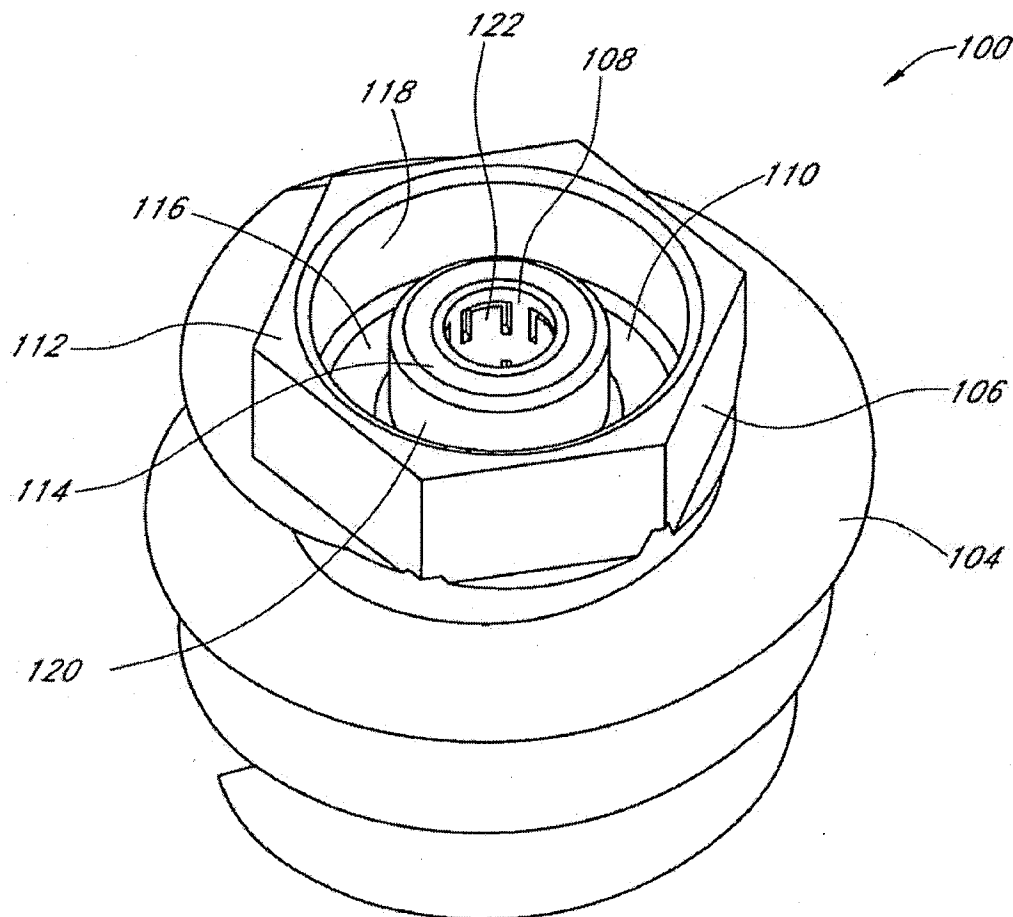


FIG. 4B

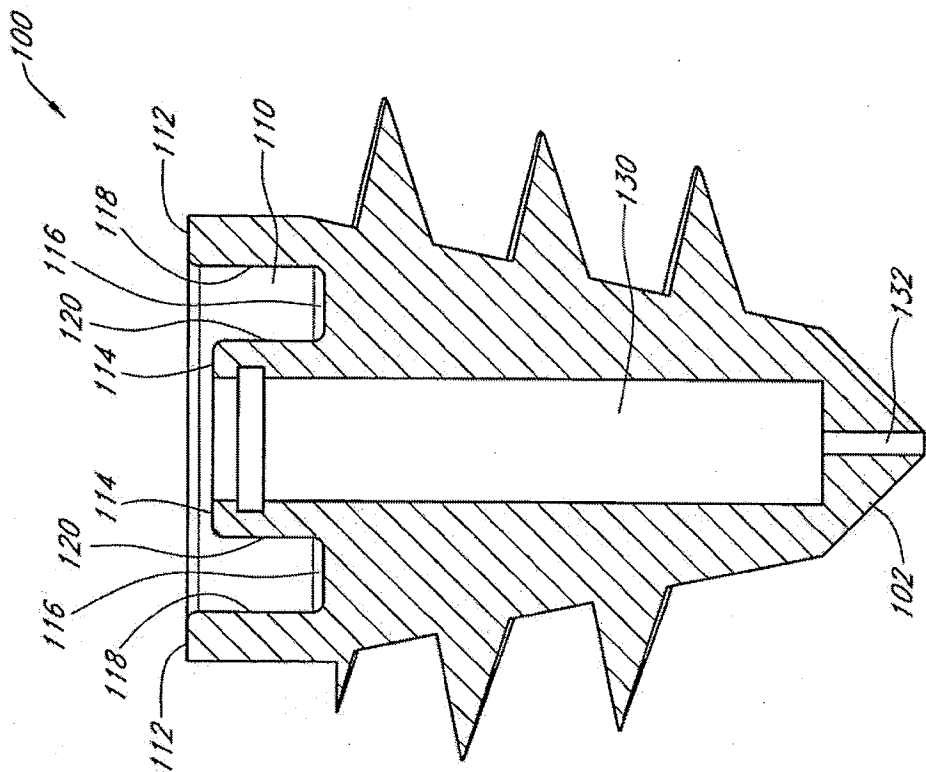


FIG. 4D

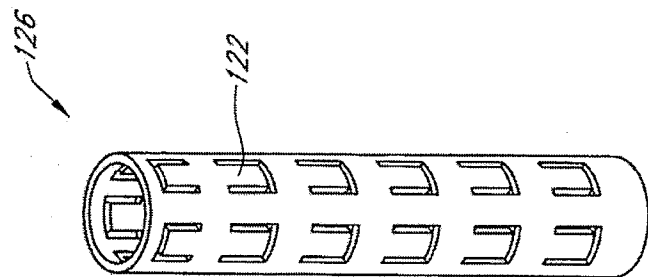


FIG. 4C

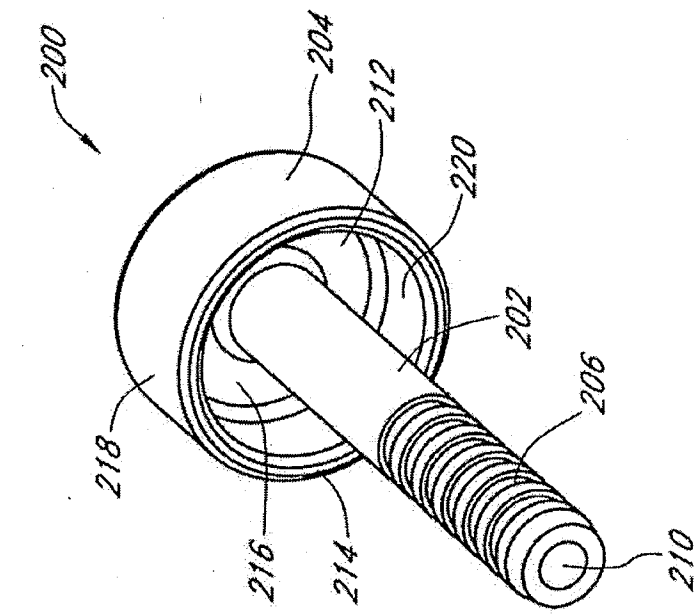


FIG. 5B

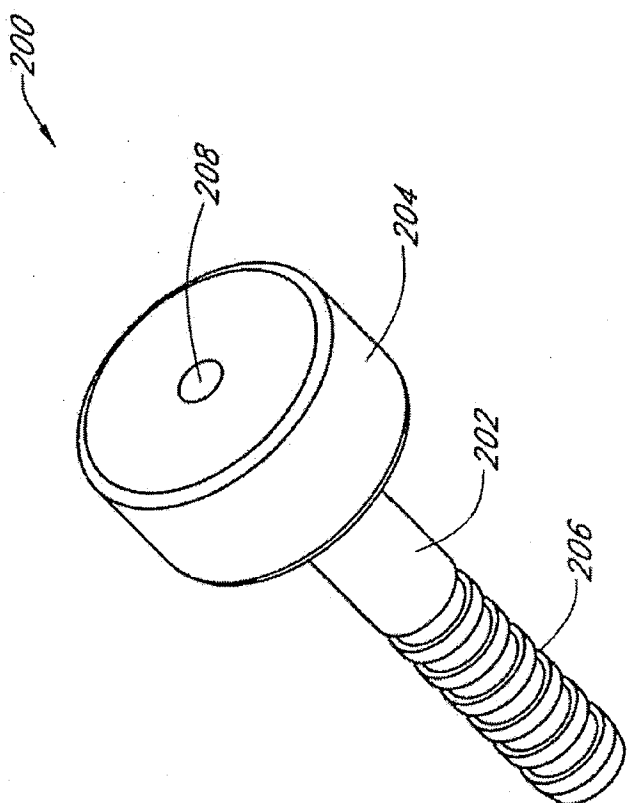


FIG. 5A



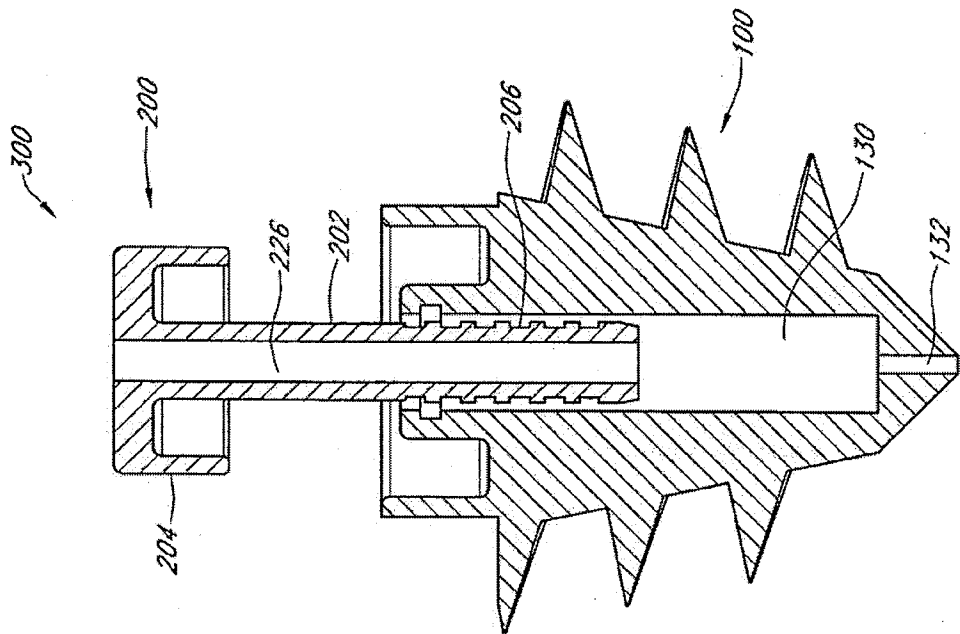


FIG. 6A

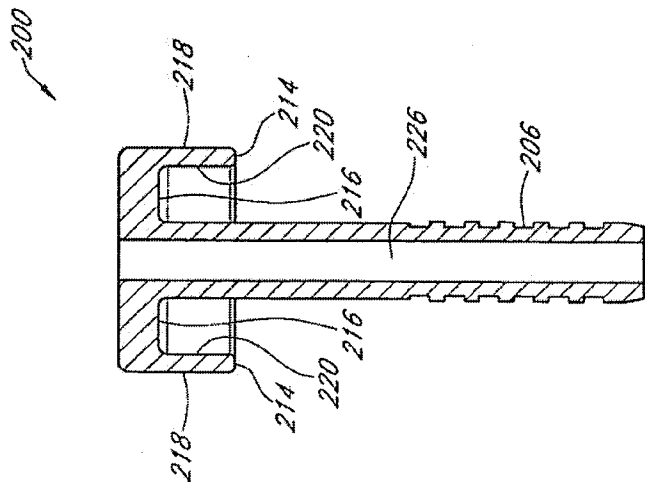


FIG. 5C

U.S. Patent

Sep. 8, 2009

Sheet 9 of 24

US 7,585,311 B2

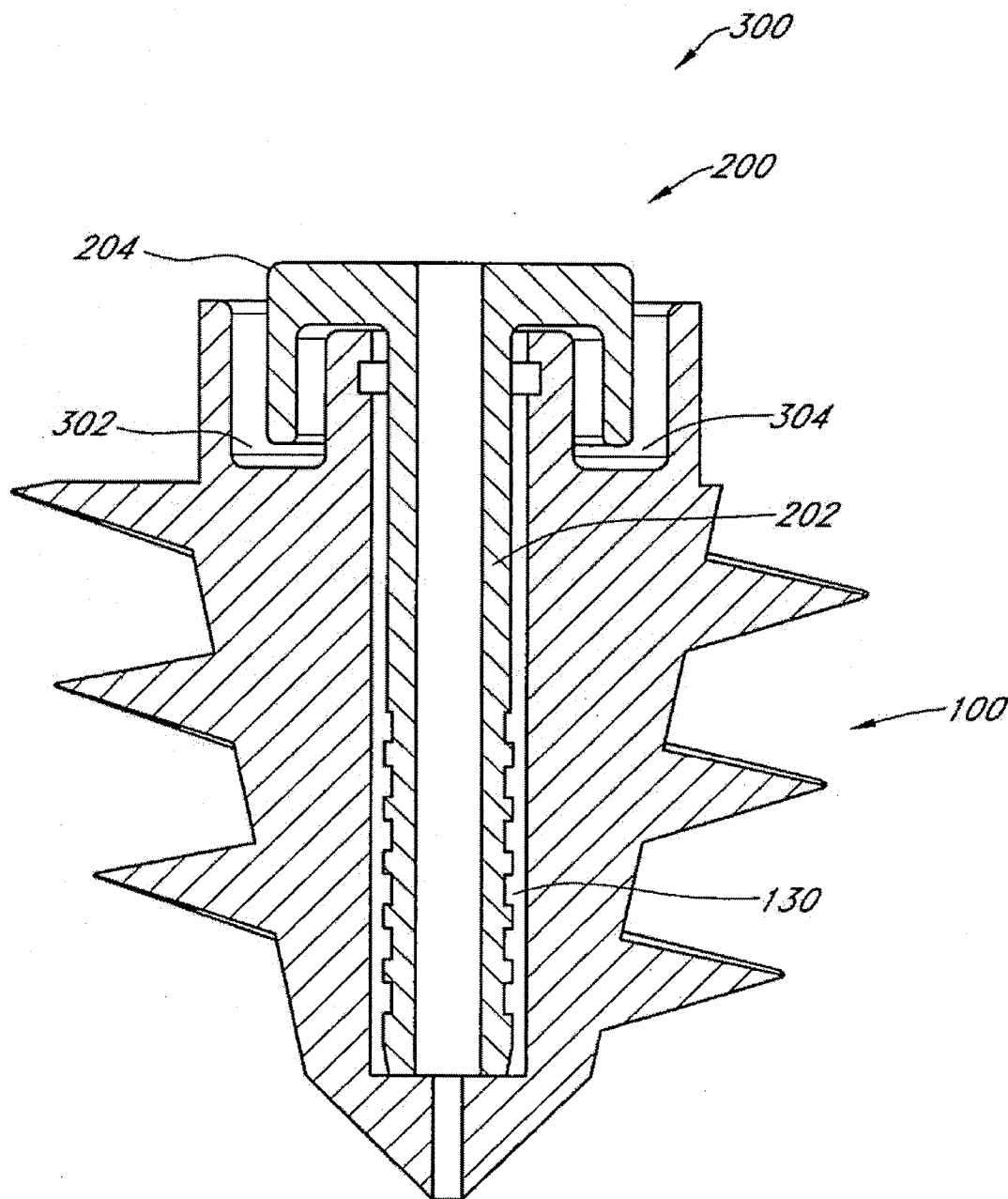


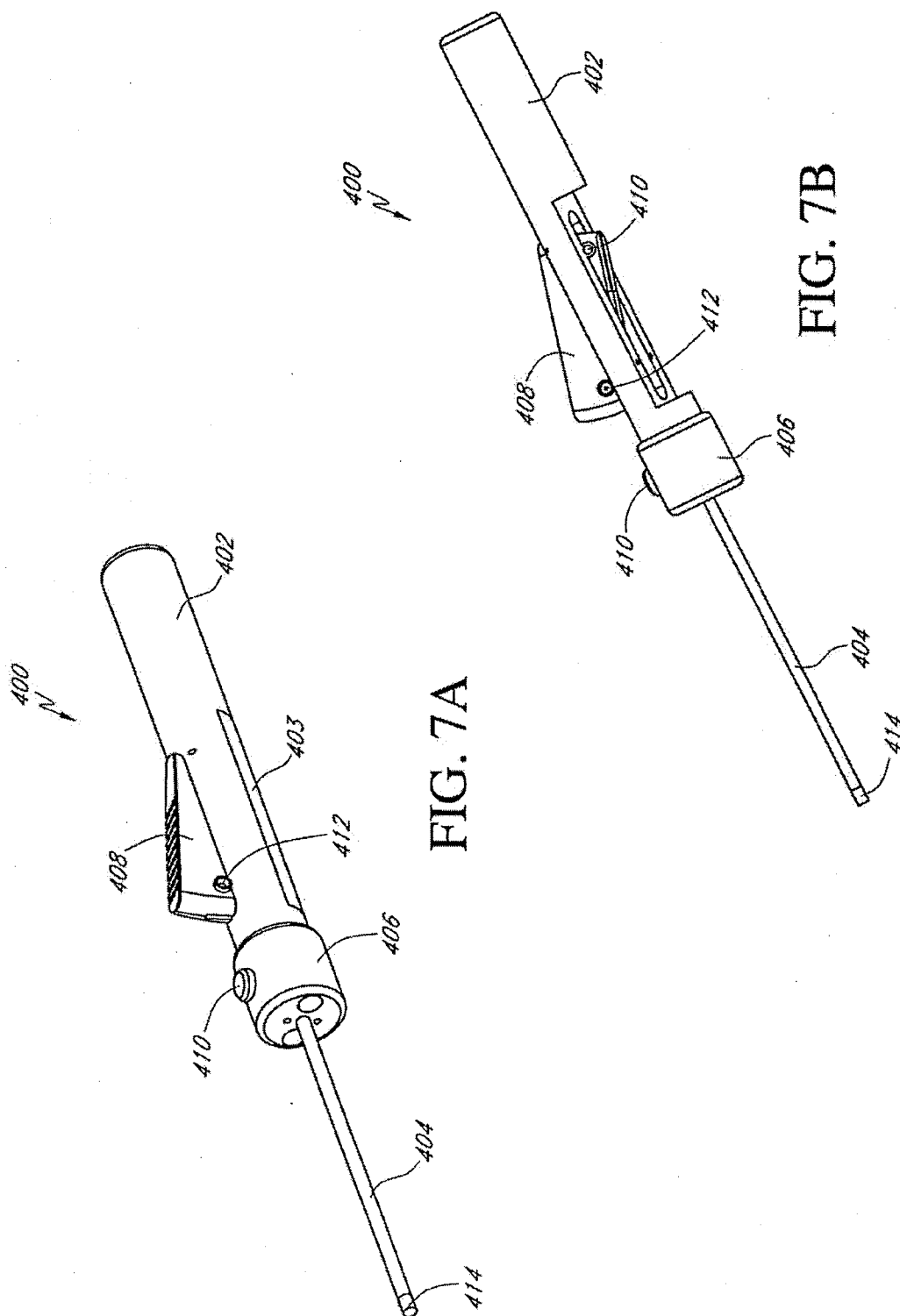
FIG. 6B

U.S. Patent

Sep. 8, 2009

Sheet 10 of 24

US 7,585,311 B2



U.S. Patent

Sep. 8, 2009

Sheet 11 of 24

US 7,585,311 B2

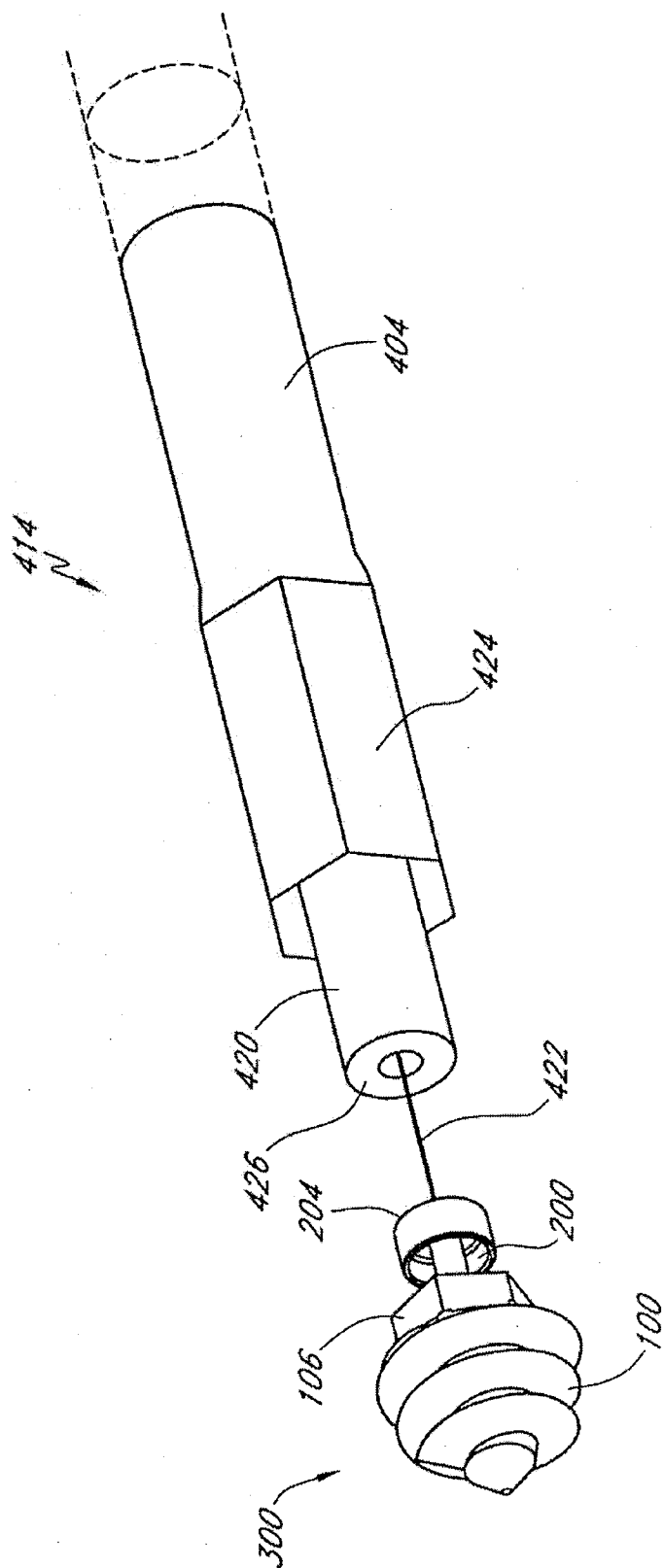


FIG. 8

U.S. Patent

Sep. 8, 2009

Sheet 12 of 24

US 7,585,311 B2

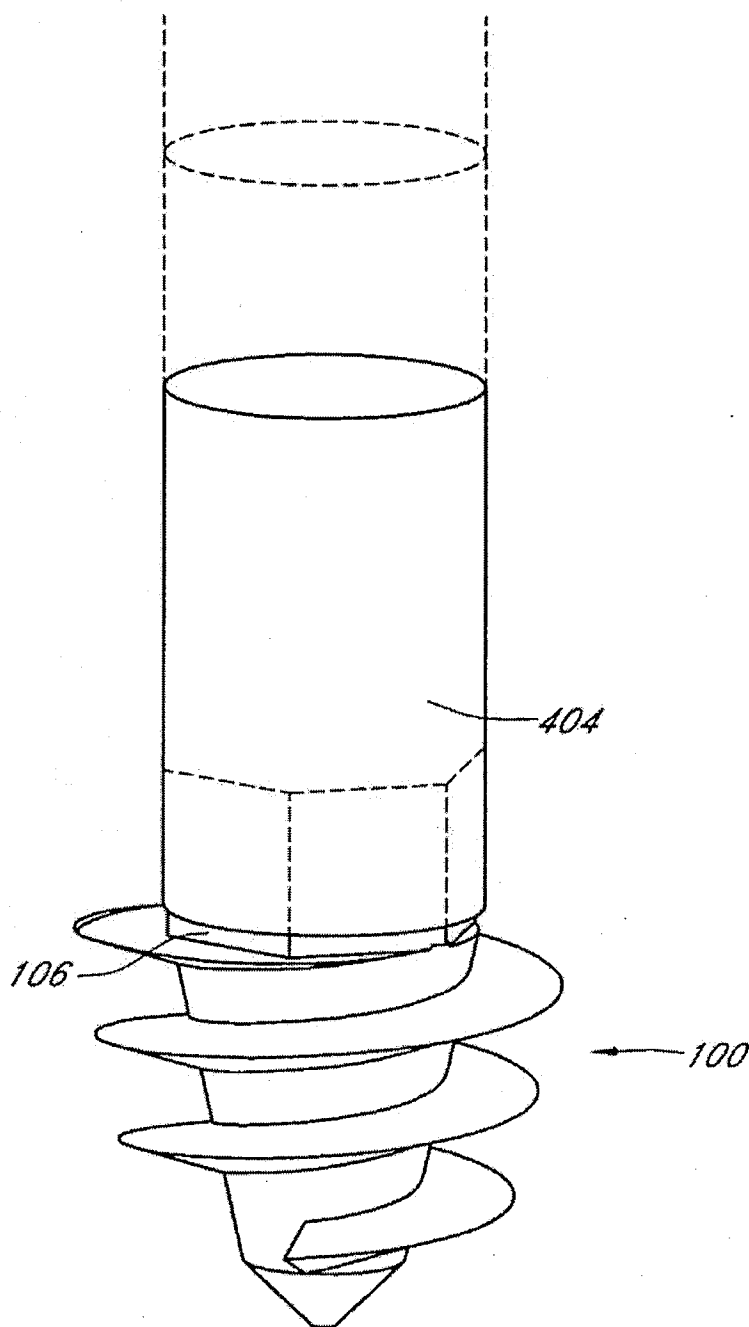


FIG. 9A

U.S. Patent

Sep. 8, 2009

Sheet 13 of 24

US 7,585,311 B2

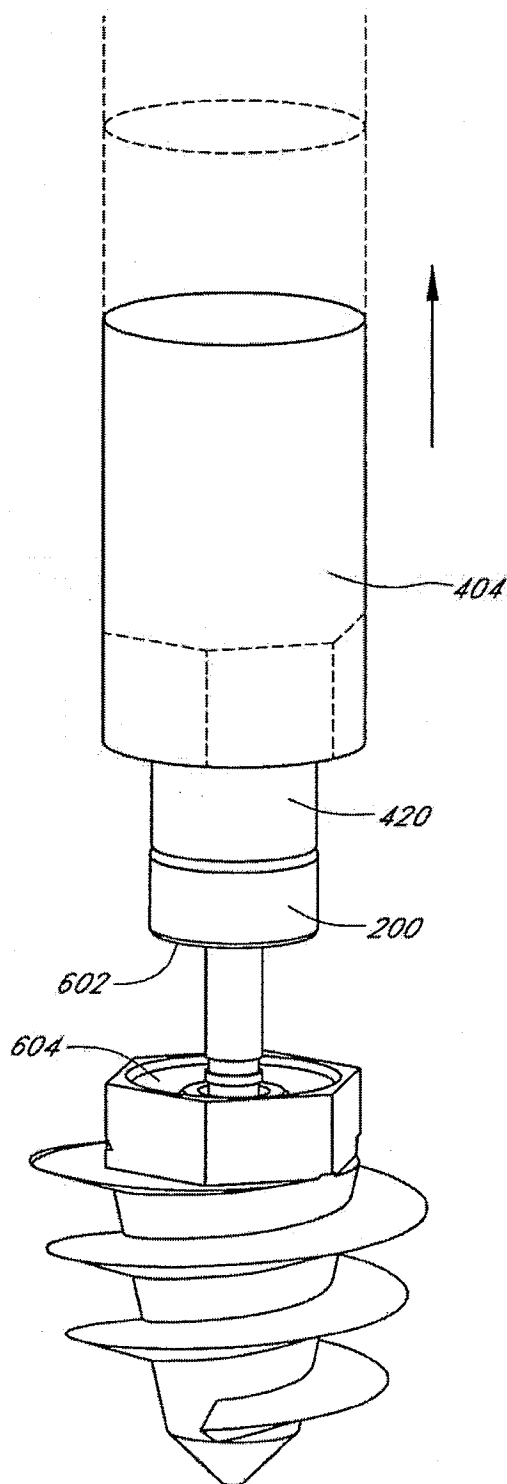


FIG. 9B

## U.S. Patent

Sep. 8, 2009

Sheet 14 of 24

US 7,585,311 B2

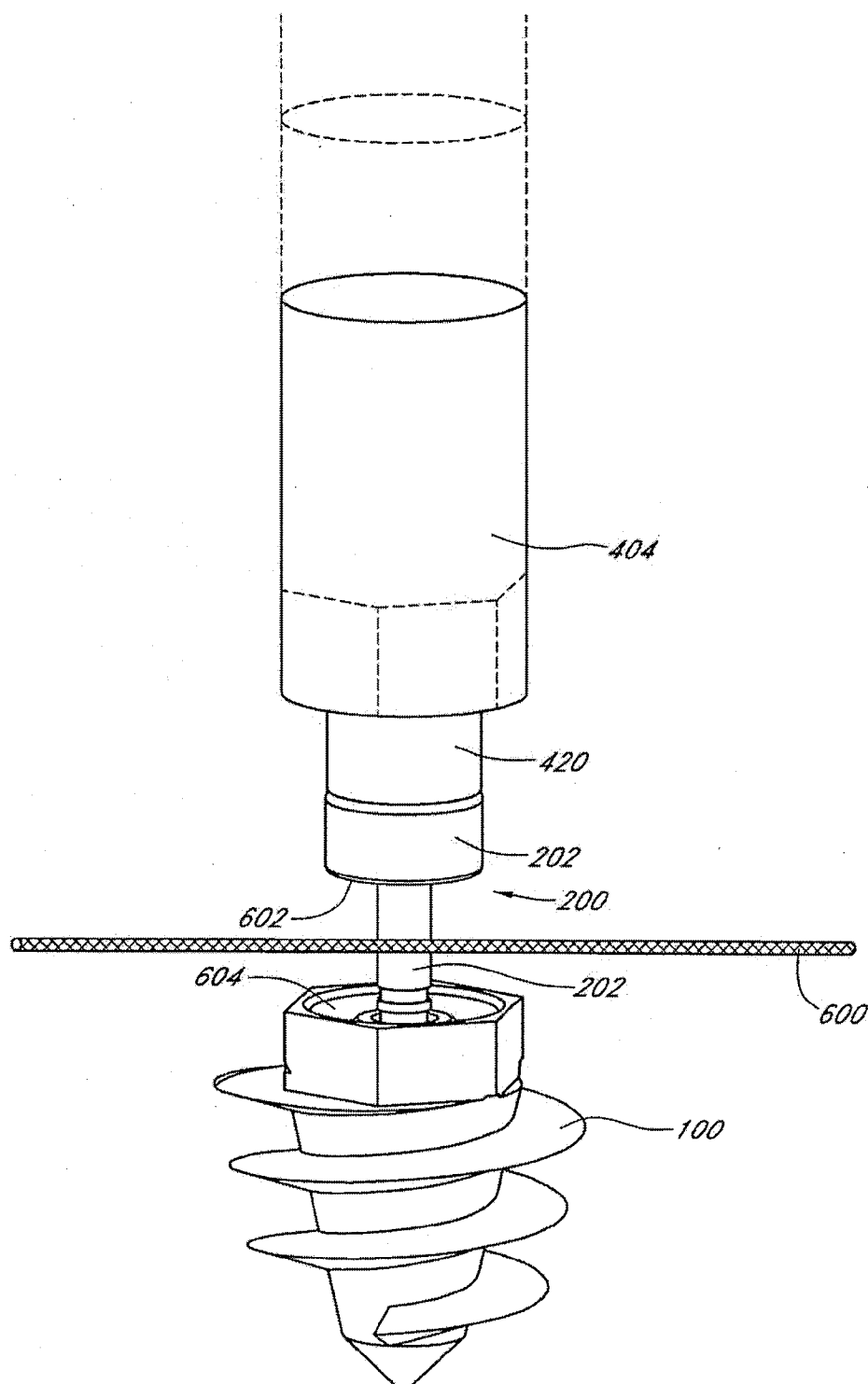


FIG. 9C

U.S. Patent

Sep. 8, 2009

Sheet 15 of 24

US 7,585,311 B2

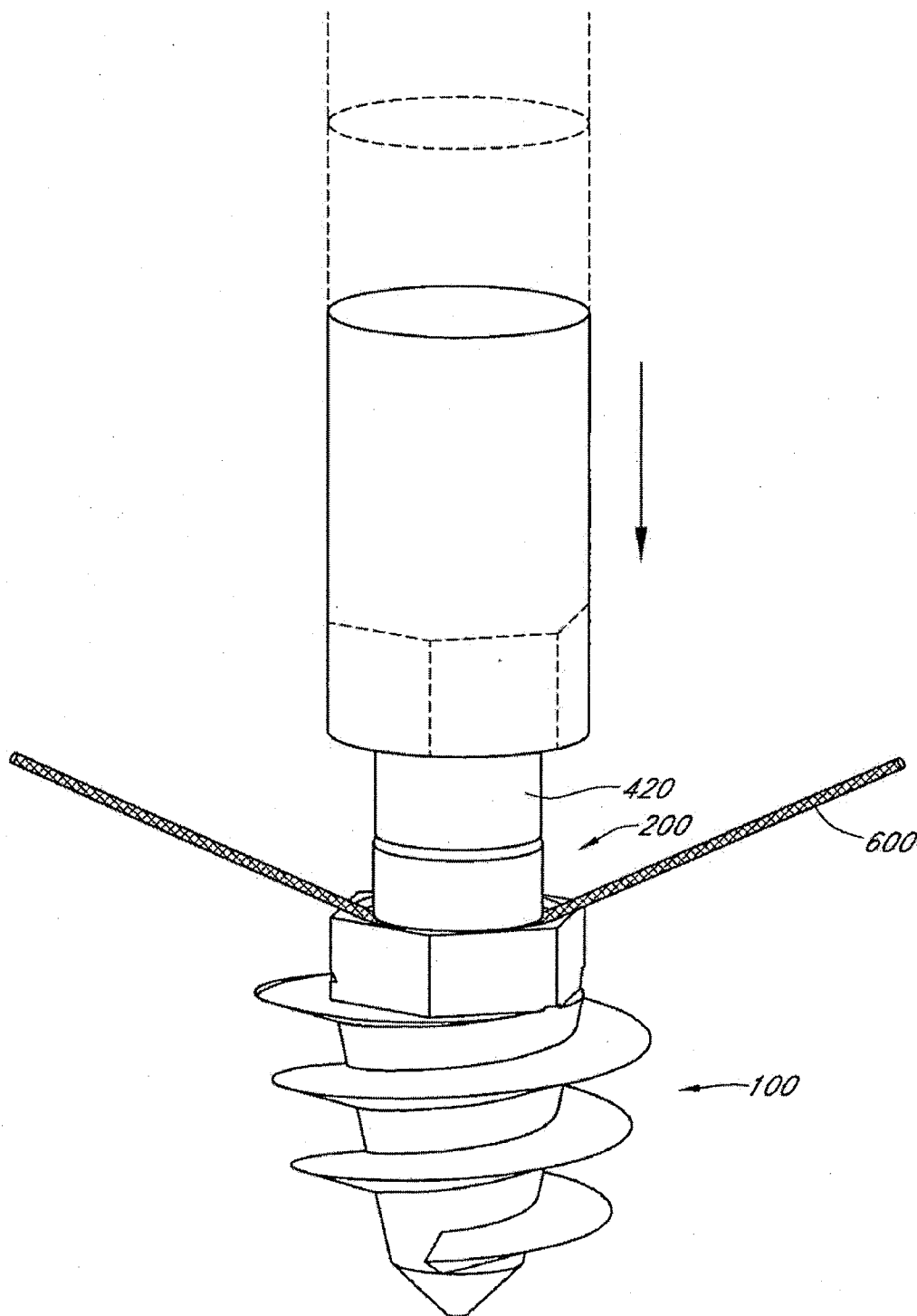


FIG. 9D



U.S. Patent

Sep. 8, 2009

Sheet 16 of 24

US 7,585,311 B2

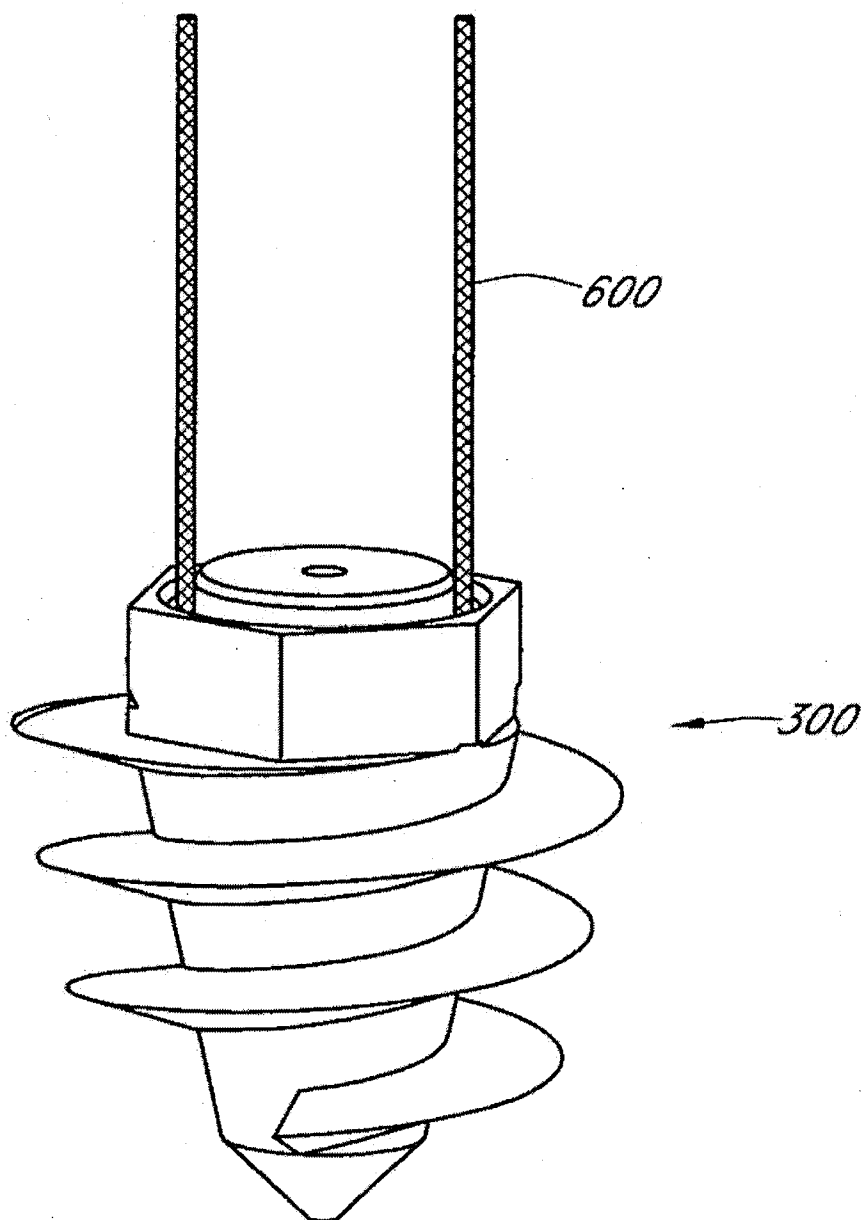


FIG. 9E

U.S. Patent

Sep. 8, 2009

Sheet 17 of 24

US 7,585,311 B2

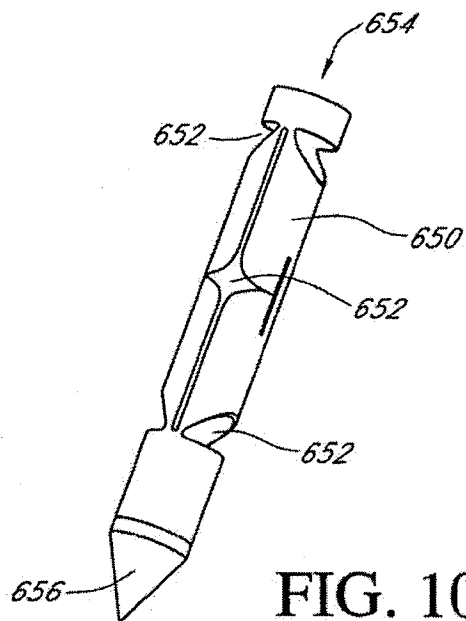


FIG. 10A

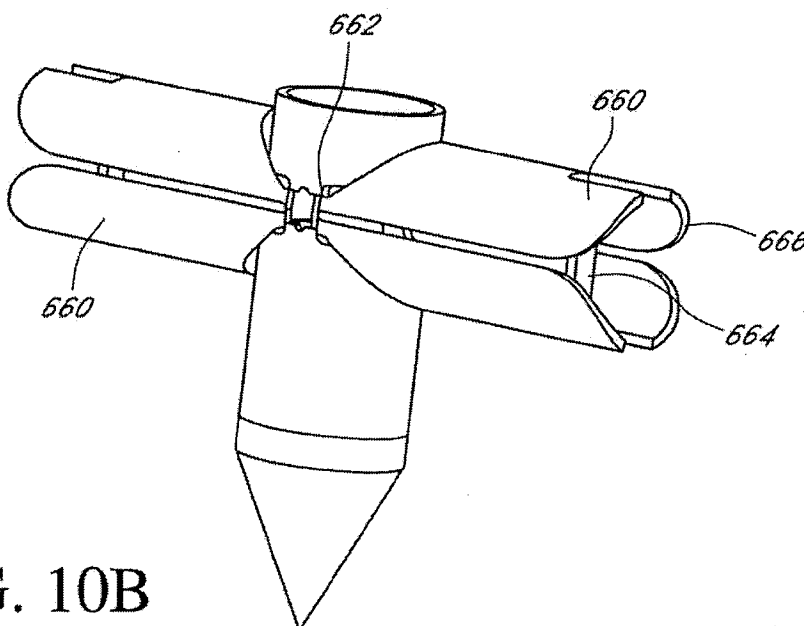


FIG. 10B

U.S. Patent

Sep. 8, 2009

Sheet 18 of 24

US 7,585,311 B2

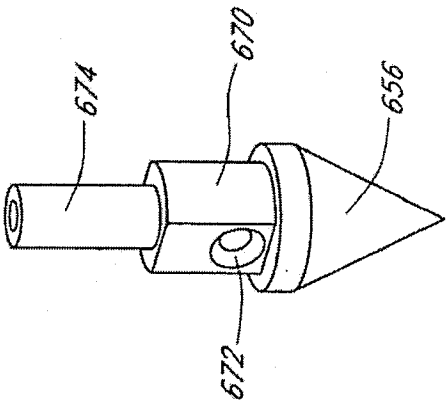


FIG. 11

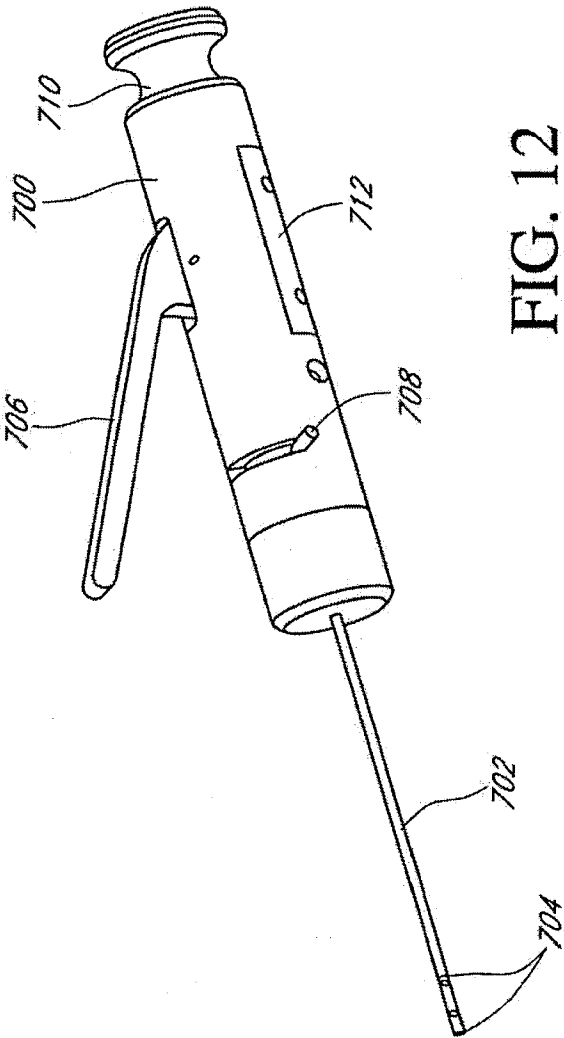


FIG. 12

U.S. Patent

Sep. 8, 2009

Sheet 19 of 24

US 7,585,311 B2

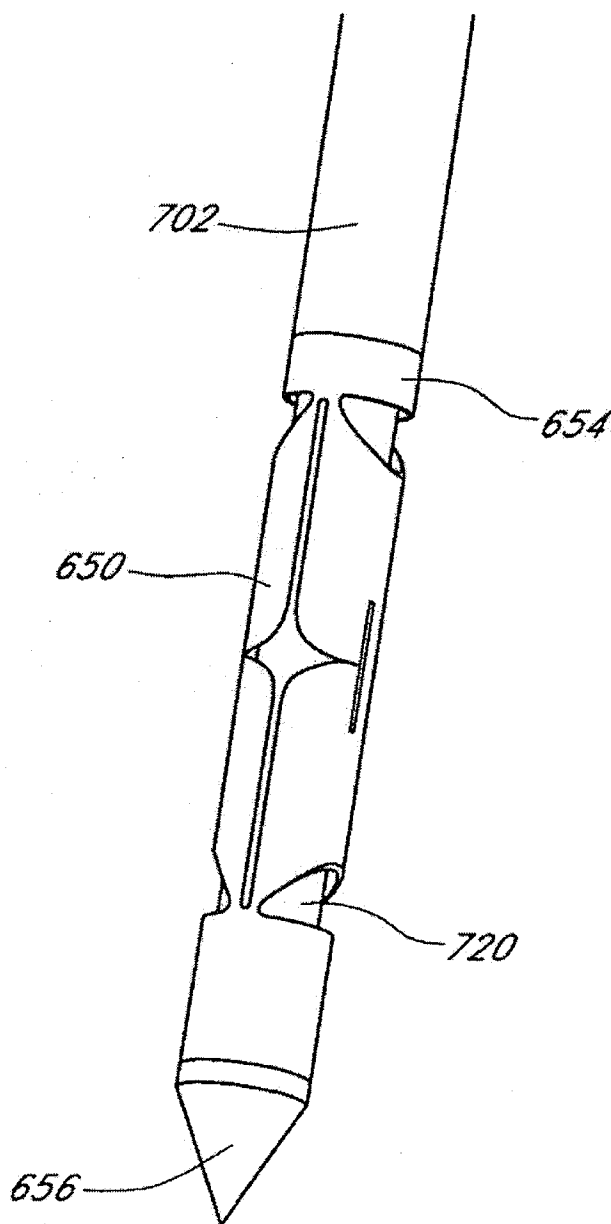


FIG. 13

U.S. Patent

Sep. 8, 2009

Sheet 20 of 24

US 7,585,311 B2

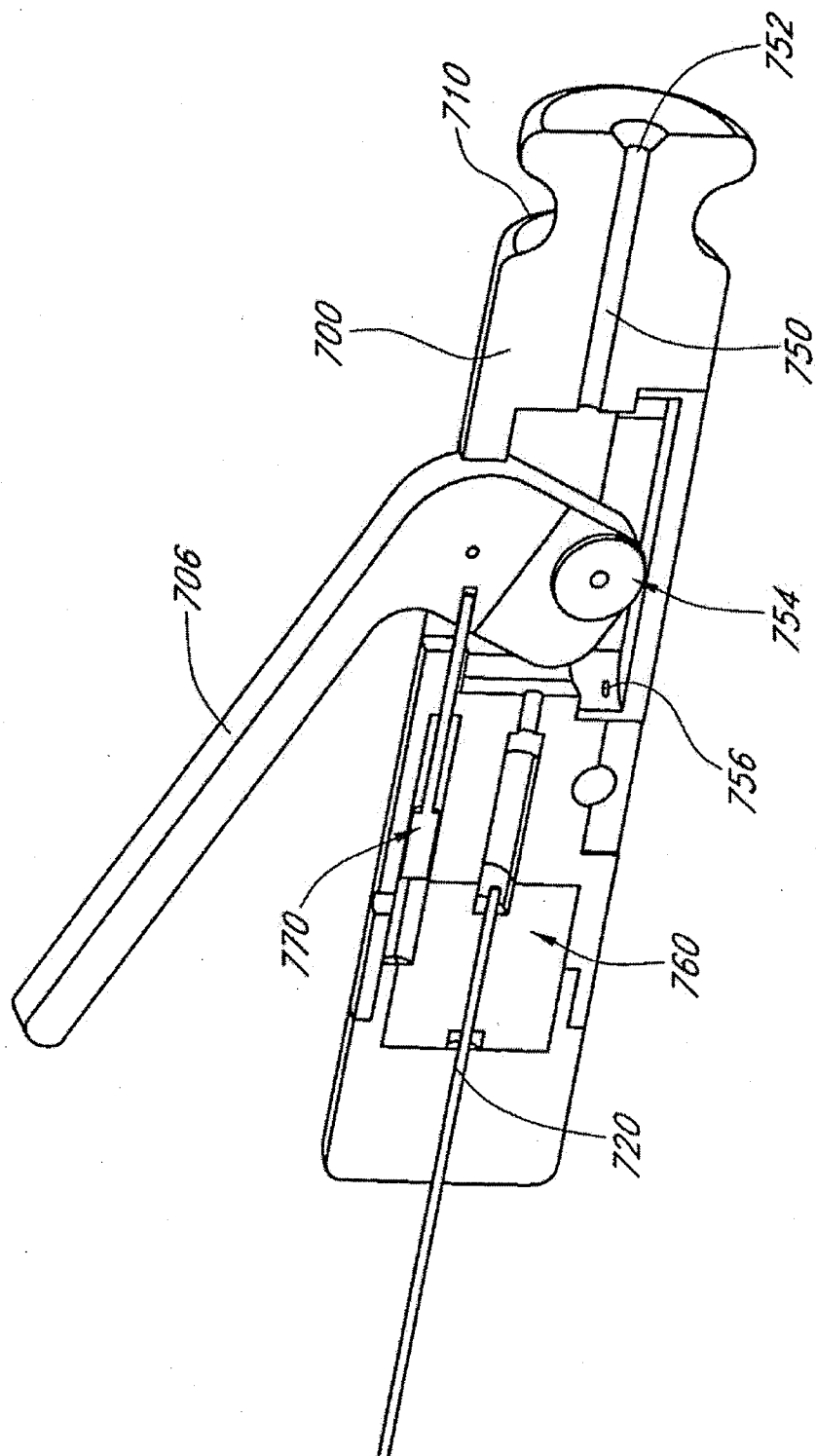


FIG. 14

U.S. Patent

Sep. 8, 2009

Sheet 21 of 24

US 7,585,311 B2

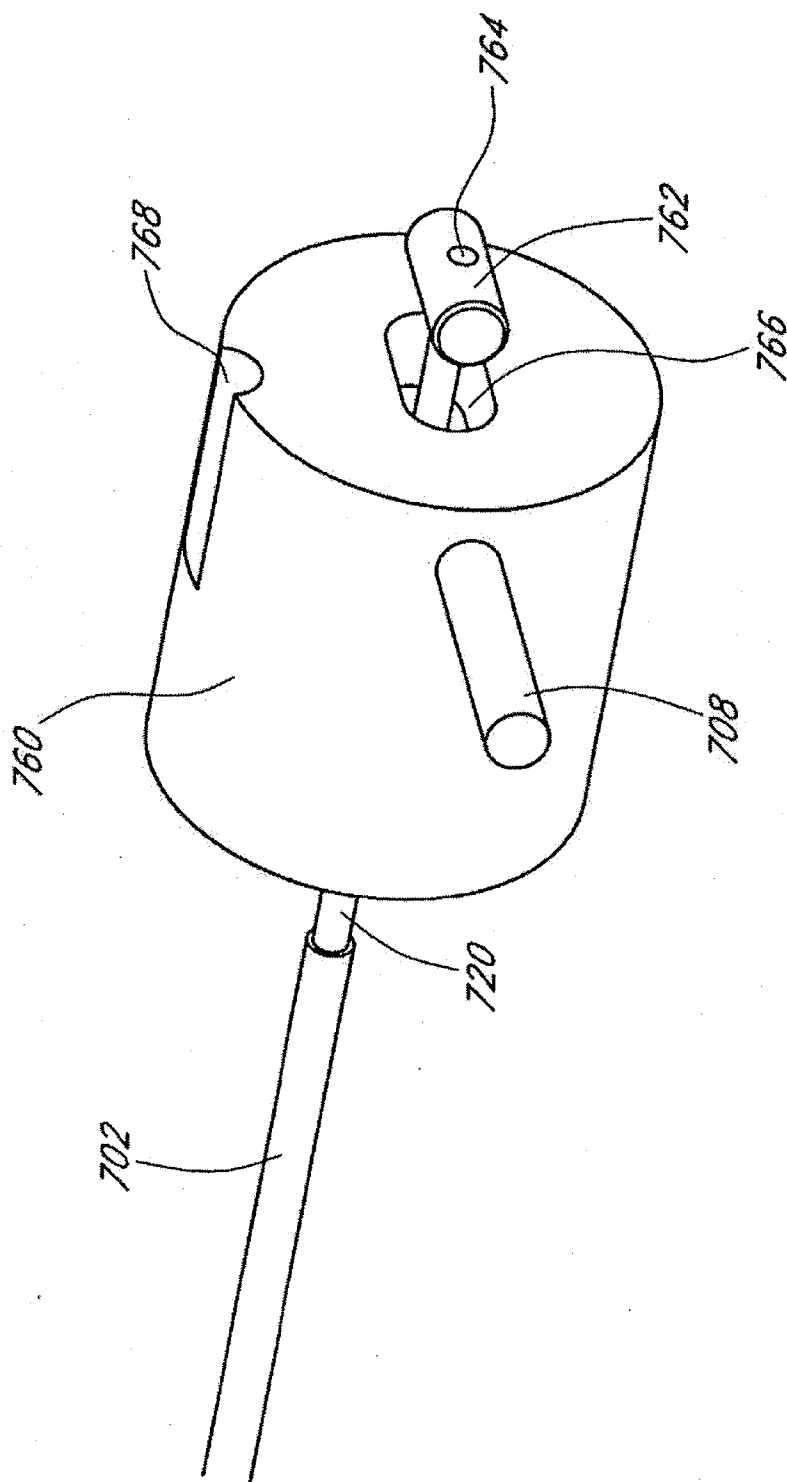


FIG. 15

U.S. Patent

Sep. 8, 2009

Sheet 22 of 24

US 7,585,311 B2

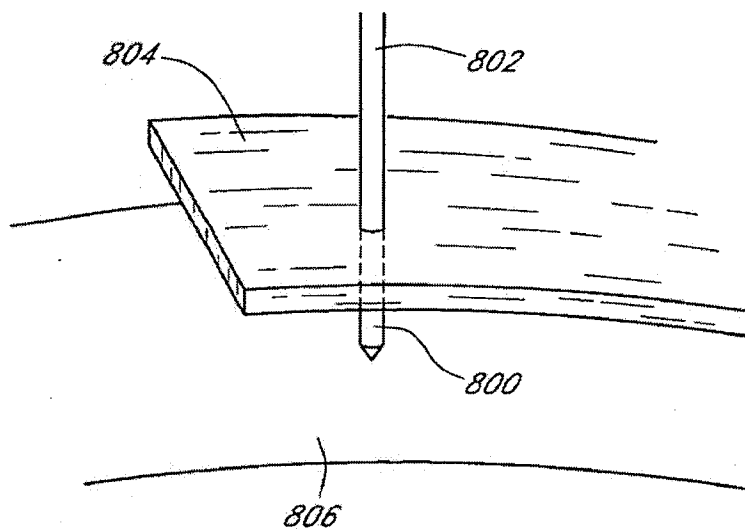


FIG. 16A

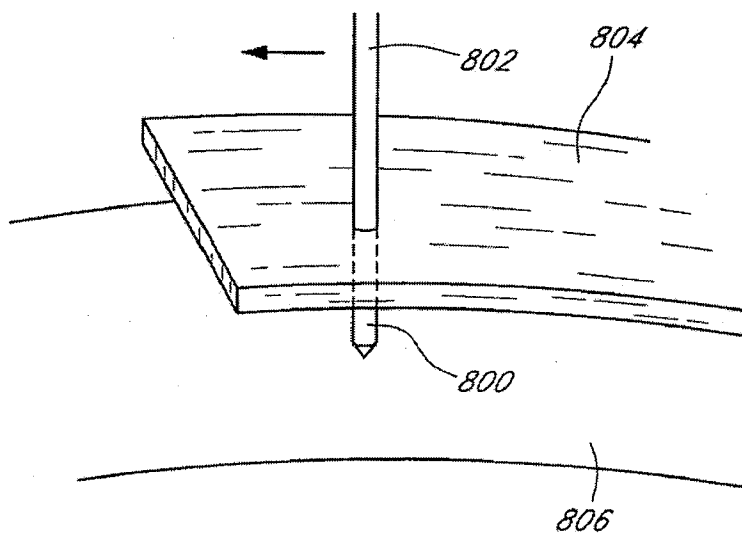


FIG. 16B

U.S. Patent

Sep. 8, 2009

Sheet 23 of 24

US 7,585,311 B2

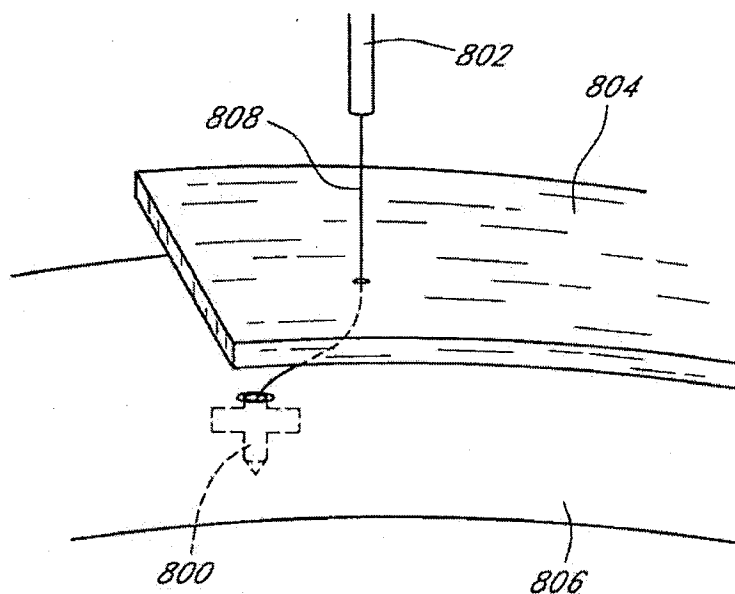


FIG. 16C

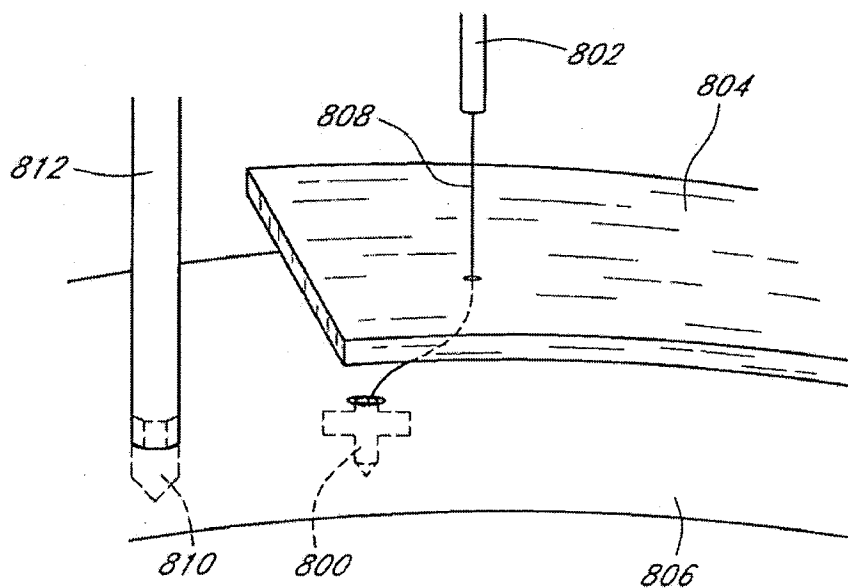


FIG. 16D



U.S. Patent

Sep. 8, 2009

Sheet 24 of 24

US 7,585,311 B2

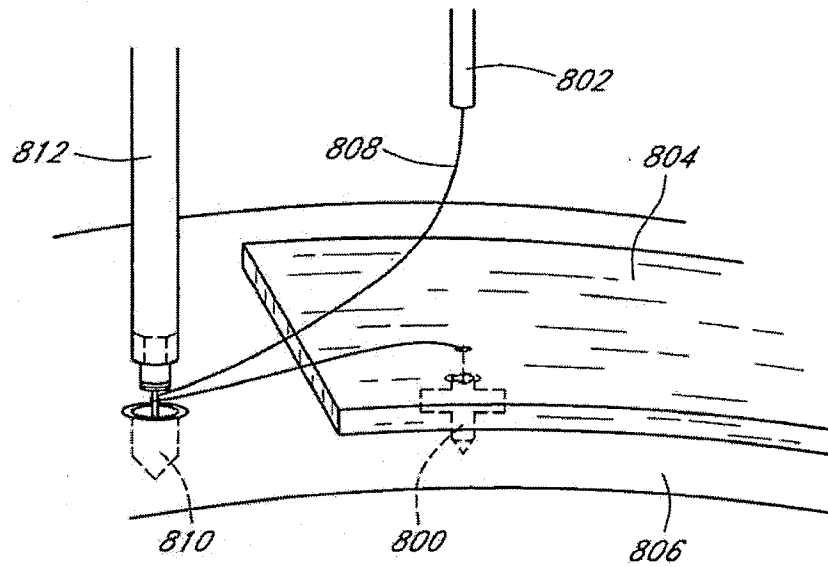


FIG. 16E

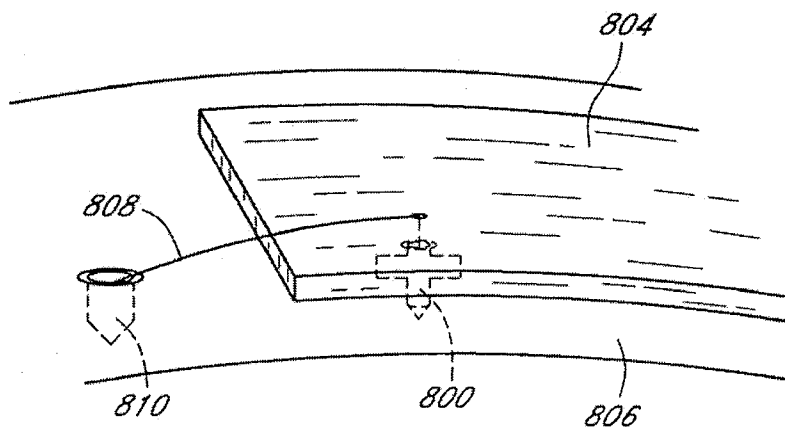


FIG. 16F

US 7,585,311 B2

1

## SYSTEM AND METHOD FOR ATTACHING SOFT TISSUE TO BONE

### RELATED APPLICATIONS

This application claims priority to U.S. Provisional Application Nos. 60/576,477, filed on Jun. 2, 2004; 60/610,924, filed on Sep. 17, 2004; and 60/634,174, filed on Dec. 7, 2004; all of which are incorporated herein by reference in their entirety.

### BACKGROUND OF THE INVENTION

#### 1. Field of the Invention

The present invention relates to medical devices and procedures. More particularly, the present invention relates to devices and methods for securing soft tissue to a rigid material such as bone.

#### 2. Description of the Related Art

There are several medical procedures where a surgeon needs to attach soft tissue such as tendons or other soft connective tissue to bone. One common example is a torn rotator cuff, where the supraspinatus tendon has separated from the humerus causing pain and loss of ability to elevate and externally rotate the arm. To repair a torn rotator cuff, typically a surgical procedure is used to suture the torn tendon to the bone using a variety of methods. Some procedures utilize large incisions and involve complete detachment of the deltoid muscle from the acromion. Small diameter holes are made in the bone for passing suture material through the bone to secure the tendon. Such large incision procedures are traumatic, causing prolonged pain and recovery time. Other procedures make small incisions and use arthroscopic techniques to attach sutures using either small diameter holes or a bone anchor. However, it is difficult to manipulate sutures within the surgical site using arthroscopic techniques. In addition, when knot tying is used to secure the suture to a bone anchor, it is difficult to properly adjust the tension of the suture while tightening the knot. Similarly, when the suture is attached to a bone anchor prior to insertion of the anchor into the bone, it is difficult to judge the appropriate point of attachment so that the suture will be properly tensioned upon insertion of the bone anchor into the bone. Thus, there is a need for methods and devices that allow easy arthroscopic attachment of a suture to a bone anchor after the anchor is inserted into the bone without the use of knot tying.

### SUMMARY OF THE INVENTION

The present invention is particularly suited for use in arthroscopic procedures, including but not limited to rotator cuff surgery. More broadly, it can be used in any procedure in which it is desired to fix a suture to a solid object without tying of knots, including not only arthroscopic procedures, but also open surgery, and can be used for such diverse purposes as bladder neck suspension, tendon and ligament affixation or repair, prosthetic attachment, and rotator cuff repair.

In one embodiment, the invention includes an anchor for securing a suture to bone, including an anchor base adapted to be securely fixed into the bone and a suture securing mechanism coupled to the anchor base and positioned proximally relative to the anchor base, the mechanism adapted to receive and secure a suture moved laterally into the

In another embodiment, the invention includes an anchor for securing a suture to bone, including an anchor base adapted to be securely fixed into the bone, a first surface coupled to the anchor base and positioned proximally relative

2

to the anchor base, and a second surface coupled to the anchor base and positioned proximally relative to the anchor base, wherein the first and second surfaces are adapted to be relatively positioned in at least two configurations, one of the configurations such that a gap is present between the first and second surfaces so that the suture can be positioned between the first and second surfaces by moving the suture laterally into the gap, and the other of the configurations such that the first and second surfaces are in close proximity so that the suture can be securely clamped between the first and second surfaces.

In another embodiment, the invention includes a method of attaching soft tissue to bone, including passing a length of suture over the soft tissue, inserting an anchor into the bone, and securing the length of suture to the anchor after the inserting without passing an end of the length of suture through any aperture in the anchor and without tying any knots.

In another embodiment, the invention includes a method of attaching soft tissue to bone, including inserting a first anchor through the soft tissue, wherein the first anchor comprises a length of suture fixedly secured to the first anchor prior to insertion, inserting the first anchor into the bone, passing the length of suture over the soft tissue, and fixedly securing, after the passing, the length of suture to a second anchor.

In another embodiment, the invention includes a method of attaching soft tissue to bone, the soft tissue comprising a first surface adjacent to the bone's surface and a second surface opposite the first surface, the method including inserting a first portion of a length of suture into the second surface of the soft tissue, passing a second portion of the length of suture over the second surface of the soft tissue, inserting a first anchor with no suture coupled thereto into the bone, and fixedly securing the length of suture to the inserted first anchor, with the proviso that no part of the first portion of the length of suture is passed out of the second surface of the soft tissue.

In another embodiment, the invention includes a method of attaching soft tissue to bone, including inserting a first anchor with a length of suture pre-coupled thereto through the soft tissue, inserting the first anchor into the bone, inserting a second anchor with no suture coupled thereto into bone, passing the length of suture over the soft tissue, and fixedly securing the length of suture to the inserted second anchor.

In another embodiment, the invention includes a method of attaching soft tissue to bone, the method including inserting a first, second, and third anchor into the bone, fixedly securing a first length of suture over the soft tissue to the first and second anchors, and fixedly securing a second length of suture over the soft tissue to the first and third anchors.

In another embodiment, the invention includes an anchor for securing a suture to bone, the anchor including an anchor base adapted to be securely fixed into the bone, the anchor base comprising a first proximal surface and an anchor top, the anchor top comprising a distal member coupled to the anchor base and a first proximal member comprising a first distal surface, wherein the anchor top is adapted to couple to the anchor base in at least two configurations, one of the configurations such that the first distal surface is above the bone's surface when the anchor base is securely fixed into the bone, such that a suture can be freely passed between the first proximal and first distal surfaces above the bone's surface, and the other of the configurations such that the first distal surface is in close proximity to the first proximal surface, such that a suture can be securely clamped between the first proximal and first distal surfaces.

US 7,585,311 B2

3

In another embodiment, the invention includes an anchor for securing a suture to bone, the anchor including a substantially hollow cylinder comprising an open end and comprising a portion of its walls cut in such a manner so as to allow the cylinder to deform under stress and form lateral protrusions, a substantially pointed tip coupled to the cylinder opposite the open end, wherein the pointed tip is adapted to pierce the bone, and a suture receiver coupled to the pointed tip and positioned within the substantially hollow cylinder so that a suture may be attached to the suture receiver and extend through the cylinder and out of the open end.

#### BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 depicts attaching soft tissue to bone using a single bone anchor and a stitch.

FIG. 2 depicts attaching soft tissue to bone using a two bone anchors with a suture stretched there between.

FIGS. 3A-3C depict various geometries of bone anchors and suture patterns for attaching soft tissue to bone.

FIGS. 4A-4D depicts the base of a two-part suture anchor that can be inserted into bone.

FIGS. 5A-5C depicts the top of a two-part suture anchor.

FIGS. 6A and 6B depict the suture anchor top of FIGS. 5A-5C inserted into the suture anchor bottom of FIGS. 4A-4D.

FIGS. 7A and 7B depict a suture anchor inserter.

FIG. 8 depicts components on a suture anchor inserter for attaching to bone and manipulating a suture anchor.

FIGS. 9A-9E depicts manipulation of a suture anchor using a suture anchor inserter to insert the suture anchor into bone and attach suture material to the suture anchor.

FIGS. 10A and 10B depict a piercing bone anchor in an un-deployed (FIG. 10A) and deployed (FIG. 10B) state.

FIG. 11 depicts a piercing bone anchor tip.

FIG. 12 depicts an anchor inserter for inserting a piercing bone anchor.

FIG. 13 depicts the interface between a piercing bone anchor and an anchor inserter.

FIG. 14 is a cut-away view of a bone anchor inserter.

FIG. 15 depicts a safety switch mechanism for a bone anchor inserter.

FIGS. 16A-16F depict a method for attaching soft-tissue to bone using a piercing bone anchor and a suture capturing anchor.

#### DETAILED DESCRIPTION OF THE CERTAIN EMBODIMENTS

In various embodiments, soft tissue may be attached to bone utilizing one or more bone anchors with suture attached thereto. As used herein, "suture" refers to any flexible structure that can be stretched between two or more anchors and includes, without limitation, traditional suture material, single or multiple stranded threads, or a mesh structure. In some embodiments, suture is passed over the top of the soft tissue so that the suture can press the soft tissue against the bone. In one embodiment, a length of suture is attached to a single bone anchor. One non-limiting example, depicted in FIG. 1, includes stitching the suture 10 to the soft tissue 12, such as by an incline mattress stitch, and then securing the suture 10 to the single bone anchor 14 that is inserted into the bone 16. However, in other embodiments, a length of suture is attached to multiple bone anchors. The use of multiple bone anchors increases the footprint over which the suture material presses the soft tissue against bone. One non-limiting example, depicted in FIG. 2, includes two bone anchors. One

4

anchor 20 is positioned in a medial location underneath the soft tissue 12 and a second anchor 22 is positioned lateral to the soft tissue 12. The suture 10 is attached to both anchors.

In one embodiment, the suture 10 is attached to the lateral bone anchor 22 only after the medial bone anchor 20 is inserted and the suture 10 is passed over the soft tissue 12. In one embodiment, the suture 10 is attached to the medial bone anchor 20 prior to insertion of the medial bone anchor 20. Thus, in this embodiment, the surgeon does not need to pass the suture through the soft tissue 12 from beneath the soft tissue 12. In one embodiment, the procedure involves inserting the medial bone anchor 20 with suture 10 pre-attached through the soft tissue 12. The medial bone anchor 20 may then be moved laterally relative to the bone 16 in order to pull the soft tissue 12 laterally relative to the bone 16. After appropriate positioning of the soft tissue 12, the medial bone anchor 20 may then be inserted into the bone 16. The lateral bone anchor 22 may then be inserted into the bone 16. The suture 12 may then be passed over the soft tissue 12 and attached to the lateral bone anchor 22. In some embodiments, a lateral bone anchor 22 is provided to which suture 12 can be attached without tying any knots or without passing the suture 12 through any aperture in the lateral bone anchor 22.

In some embodiments, multiple anchors and multiple suture lengths may be used to provide a wider area of pressure of the soft tissue against bone. For example, as depicted in FIG. 3A, three anchors are used with two lengths of suture 26 and 28. Alternatively, a mesh structure 29 may be stretched between the three anchors. In another example, as depicted in FIG. 3B, four anchors are used with two lengths of suture. In still another example, as depicted in FIG. 3C, four anchors are used with four lengths of suture. In some embodiments, the individual suture lengths may be part of a larger continuous suture. For example, in FIG. 3A, the suture lengths 26 and 28 may be part of a larger length of suture such that the lengths 26 and 28 are joined at medial bone anchor 20. Those of skill in the art will appreciate that there are any number of anchor and suture geometries that can be used.

In some embodiments, the medial bone anchors 20 are designed so that they can be easily pierced through the soft tissue 12 and bone 16. In some embodiments, the lateral bone anchors 22 are designed so that they can easily capture suture material after insertion of the bone anchors 22. Together, these design features provide a suturing system and method that provides an increased footprint of suture pressure against the soft tissue 12 and ease of implementation for a surgeon. For example, in some embodiments, the entire procedure may be done arthroscopically, with the surgeon needing only to insert the medial bone anchor 20 with suture optionally pre-attached through a first port, insert the lateral anchor 22 through a second port, pass the suture over the soft tissue 12 by capturing it from within the second port, and securing the suture to the lateral anchor 22. Accordingly, described below are certain embodiments of anchors adapted to capture suture material and anchors adapted to easily pierce through soft tissue and bone.

#### Suture Capturing Anchor

One embodiment is a bone anchor that allows easy capturing and securing of a suture after the bone anchor is inserted into the bone. In one embodiment, the bone anchor includes a suture securing mechanism positioned on the proximal end of the bone anchor (i.e., the end nearest the surface of the bone and the surgeon). In one embodiment, the suture securing mechanism allows a suture to be moved laterally into the mechanism. By "laterally," it is meant that the suture can be moved into the mechanism by moving the suture in a direc-



US 7,585,311 B2

5

tion that is generally perpendicular to the axis of the suture. In other words, the suture can be moved into the mechanism without threading an end of the suture into the mechanism. In one embodiment, the suture can be fixedly secured within the mechanism without tying any knots. By "fixedly secured," it is meant that the suture within the securing mechanism cannot be easily moved relative to the bone anchor.

One embodiment is a bone anchor that allows easy attachment of suture material by clamping the suture material between two surfaces on the bone anchor. The bone anchor may be configured such that the bone anchor is inserted into the bone without the suture material attached. The two surfaces of the suture securing mechanism may be spaced apart so as to form a gap between the surfaces. The suture material may be passed between the two surfaces and tensioned as desired followed by clamping of the two surfaces together, thereby clamping the suture material there between.

In one embodiment, the bone anchor consists of two parts: an anchor base and an anchor top. The anchor base may be designed to be inserted into a hole in the bone with a proximal surface facing up. The anchor top may be coupled to the anchor base via a distal member. A proximal member on the anchor top may have a distal surface facing down toward the proximal surface on the anchor base. The coupling of the anchor top to the anchor base may be such that the anchor top can move relative to the anchor base such that it can be positioned in one configuration where there is space between the proximal surface on the anchor base and the distal surface on the proximal member of the anchor top. In another configuration, the proximal member of the anchor top may be positioned such that there is very little space, if any, between the proximal surface on the anchor base and the distal surface on the proximal member of the anchor top. Thus, in the first configuration, suture material may be easily passed between the two surfaces and tensioned as desired. In the second configuration, the suture material may be clamped between the two surfaces such that the suture is secured to the bone anchor.

One embodiment of an anchor base 100 is depicted in FIGS. 4A through 4D. FIG. 4A is a perspective view showing the side 101 and bottom 102 of the anchor base 100. The bottom 102 of the anchor base 100 may advantageously be tapered to facilitate insertion of the anchor base 100 into bone. In some embodiments, a hole is predrilled into the bone to facilitate insertion of the anchor base 100. In other embodiments, the anchor base 100 is forced directly into the bone, thereby creating the hole. The sides 101 of the anchor base 100 comprise threads 104 so that the anchor base 100 may be inserted into bone using a screwing action. In some embodiments, the anchor base 100 may be tapped to start the threads 104 into the bone followed by screwing the anchor base 100 into the bone. When the hole in the bone is pre-drilled, the hole is advantageously drilled with a diameter smaller than the diameter of threads 104 so that the threads engage the bone through the sides of the hole. It will be appreciated that means other than threads may be used to secure the anchor base 100 to bone. For example, angled protrusions may be used that provide greater resistance to removal of the anchor base 100 than to insertion. The protrusions may be static or deployable once the anchor is inserted.

The top of anchor base 100 preferably includes a structure 106 for facilitating the driving or screwing of the base 100 into the bone. In the illustrated embodiment, this comprises a hex nut structure 106 that facilitates engagement with a hex nut driver for screwing the anchor base 100 into the bone. It will be appreciated that other structures known in the art for engaging tools used for screwing action may be used instead

6

of hex nut structure 106, and that this structure can be indented into or extending out from the top of the anchor base 100, or can alternatively be formed on the sides of the anchor base 100.

With reference to FIG. 4B, which is a perspective view of the top and side of anchor base 100, the top (proximal end) comprises a hole 108 in the center for receiving the anchor top, which is described below. The top of anchor base 100 also contains a suture gripping structure such as a circular groove 110 that may be concentric with hole 108. Because of groove 110, the proximal surface of anchor base 100 is not flat and comprises top surfaces 112 and 114, bottom surface 116, and side surfaces 118 and 120. In some embodiments, some or all of these surfaces may be textured such as with a scallop shape or grooves so as to inhibit movement of suture material pressed against the surfaces. Although a grooved surface is illustrated, it will be appreciated that other shapes for the proximal surface of anchor base 100 are also contemplated, including multiple concentric grooves, a series of protruding ridges, a "vee" shaped channel, or any other suitable structure that permits a suture to be securely locked against the top or proximal end of the anchor base 100.

Hole 108 in anchor base 100 is an opening into a central ("axial") bore into the anchor base 100. The sides of the central bore preferably include structures for gripping something inserted into the central bore, such as ratchet structures 122. FIG. 4C shows a central ratchet bushing 126 that fits within the central bore and contains the ratchet structures 122. In the embodiment of FIG. 4C, the ratchet structures 122 are constructed by cutting U shaped cuts into bushing 126. The U shaped cuts then define tabs that make up the ratchet structures 122. It will be appreciated that other shapes and methods for making ratchet structures may be used. The purpose of ratchet bushing 126 is to receive the anchor top and secure it to the anchor base 100. It will be appreciated that other methods of securing the anchor top to the anchor base 100 may be used, such as a frictional fit or threading. Furthermore, the anchor top may be coupled to the anchor base 100 using means other than hole 108 and bushing 126. For example, the anchor top may be coupled via structures at the perimeter rather than the center or by a hinge.

FIG. 4D depicts a cross section through the center of anchor base 100. This view illustrates central bore 130 and groove 110. The proximal surfaces 112, 114, 116, 118, and 120 are also apparent. Central bore 130 preferably does not extend all the way through the anchor base 100. Instead, a smaller bore 132 is present at the distal end 102 of the anchor base 100. Smaller bore 132 is used to receive a wire connected to an anchor inserter. It will be appreciated that other structures than bore 132 may be used for attaching the wire and that other means than a wire may be used to secure the anchor to the anchor inserter.

FIGS. 5A through 5C illustrate one embodiment of an anchor top 200. FIG. 5A provides a perspective view of the side and top of the anchor top 200 and FIG. 5B provides a perspective view of the side and bottom of the anchor top 200. Anchor top 200 has two members, a distal member 202 and a proximal member 204. The distal member 202 comprises an elongated shaft, the longitudinal direction of which shall be considered to run along the axis of the distal member 202. A series of grooves or other mating or locking surfaces or structures 206 exist along a portion of the outside surface of the shaft. The distal member 202 is designed to be inserted into the central bore 130 of the anchor base 100. The ratchet structures 122 in the anchor base 100 engage grooves 206 to couple the anchor top 200 to the anchor base 100. The ratchet structures 122 are oriented such that the distal member 202

US 7,585,311 B2

7

can be easily moved in the distal direction in central bore 130 with the ratchet structures 122 snapping into the grooves 206 as the distal member 202 is moved downward. However, when the ratchet structures 122 are snapped into grooves 206, proximal movement of distal member 202 is inhibited. Thus, the anchor top 200 may be ratcheted down into anchor base 100. Because the ratchet structures 122 exist along substantially the entire surface of the central bore 130 (see FIG. 4C), the anchor top 200 may be coupled to the anchor base 100 in several positions. In other words, in one embodiment the anchor top 200 need not be ratcheted into the anchor base 100 as far as it will go for it to be secured to the anchor base 100.

The proximal member 204 of anchor top 200 is generally cylindrical in shape with a diameter larger than distal member 202. A hole 208 may advantageously be provided in the center of proximal member 204. With reference to FIG. 5B, the bottom of distal member 202 also contains a hole 210. Holes 208 and 210 open into a central bore through the anchor top 200. This central bore allows the wire referred to above to extend through the anchor top 200 to be secured to bore 132 in the anchor bottom 100, thus allowing the anchor bottom 100 to be attached to an anchor inserter while still allowing anchor top 200 to be ratchet into anchor bottom 100. FIG. 5B also illustrates that proximal member 204 contains a groove 212 in its distal surface. Thus, the distal surface of proximal member 204 is not flat and comprises distally facing surfaces 214 and 216 and side facing surfaces 218 and 220. In some embodiments, some or all of these surfaces may be textured such as with a scallop shape or grooves so as to inhibit movement of suture material pressed against the surfaces. In some embodiments, texturing in the distal surfaces of proximal member 204 match texturing in the proximal surfaces of anchor base 100. It will be appreciated that the illustrated embodiments represent only one possibility; thus, other shapes for the distal surface of proximal member 204 may also be used. FIG. 5C depicts a cross section through the center of anchor top 200. In this figure, the central bore 226 is depicted as are surfaces 214, 216, 218, and 220 and grooves 206.

FIGS. 6A and 6B depict cross sections showing how the anchor top 200 may be coupled to anchor base 100 to form the complete anchor 300. In FIG. 6A, the anchor top 200 is coupled to anchor base 100 with the proximal member 204 separated from the anchor base 100. The anchor top 200 is secured to anchor base 100 by distal member 202 extending into central bore 130 of the anchor base 100. The distal member 202 is secured by ratchet structures (not shown) engaging grooves 206 in distal member 202. Central bore 226 in anchor top 200 and central bore 130 in anchor base 100 allow a wire to extend into the top of the anchor 300 and be secured to bore 132. Alternatively, the wire may be secured at other locations within central bore 130. Thus the wire, which can be coupled to an anchor inserter, can hold the entire anchor assembly 300 and still allow anchor top 200 to move relative to anchor base 100 and the wire.

FIG. 6B depicts the anchor assembly 300 with the distal member 202 of anchor top 200 ratcheted all the way into central bore 130 in anchor base 100. In this configuration, it can be seen that proximal surfaces 112, 114, 116, 118, and 120 of the anchor base 100 and distal surfaces 214, 216, 218, and 220 of the proximal member 204 of anchor top 200 form passageways 302 and 304. The size of passageways 302 and 304 are advantageously such that when a suture passes through them, it will be compressed so that it is securely attached to the anchor 300.

Another embodiment of the present invention is an inserter designed to insert and manipulate an anchor such as described

8

in FIGS. 1-3. One such inserter 400 is depicted in FIGS. 7A and 7B. Inserter 400 comprises a handle 402 and an outer tube 404. As depicted in FIG. 7A, the handle 402 comprises a cover 403. FIG. 7B depicts the inserter 400 with cover 403 removed. Not depicted in FIGS. 7A and 7B are an inner tube disposed inside outer tube 404 and a wire disposed within the inner tube. As will be described in more detail below, the inner and outer tubes may be used to manipulate an anchor 300 such as that described in FIGS. 4-6. The wire may be used to couple the inserter 400 to the anchor 300 as described above. Inserter 400 also comprises an outer tube manipulator 406 and a wire manipulator 408. Outer tube manipulator 406 comprises release button 410. Outer tube manipulator 406 is securely attached to outer tube 404. Outer tube manipulator 406 may move longitudinally relative to handle 402 and the inner tube when release button 410 is pressed. Thus, when outer tube manipulator 406 is moved, outer tube 404 also moves.

Wire manipulator 408 comprises wire grabber 410 to which the wire is attached. The wire extends from wire grabber 410, through handle 402, and then through the inner tube. In one embodiment, wire manipulator 408 also comprises a release button 412. When release button 412 is pressed, the wire manipulator 408 may be pressed into the handle 402 to contact and thus provide additional tension on the wire. When in use, the additional tension causes the anchor base 100 to move relative to inserter 400. When enough tension is provided to the wire by wire manipulator 408, the wire may break free from the anchor 300 at its attachment point in bore 132 or at some other predetermined location along the wire. It will be appreciated that any suitable breakable attachment means may be used for securing the wire to the anchor 300. For example, the wire may be frictionally secured into bore 132 or it may be welded to the anchor base 100 using a weld that is weaker than the wire itself or a portion of the wire where breaking is desired may be weakened. In one embodiment, the wire is notched so as to create a weaker region in the wire that will break upon application of suitable force.

The tip 414 of outer tube 404 is depicted in more detail along with inner tube 420, wire 422, and anchor 300 in FIG. 8. The end of outer tube 404 may comprise a hex nut driver structure 424 for receiving the hex nut structure 106 of anchor base 100. Of course, any other suitable engagement structure can be provided on the inserter 400 and the anchor base 100 in order to facilitate placement of the anchor base 100. Wire 422 extends out of inner tube 420 and into the central bore in the anchor top 200 to attach to anchor base 100 as described above. In some advantageous embodiments, the wire length and tension is adjusted such that the proximal member 204 of anchor top 200 butts against the end 426 of inner tube 420.

FIGS. 9A through 9E depict how inserter 400 and anchor 300 may be used to insert the anchor 300 into bone and attach a suture to it. FIG. 9A depicts the configuration for inserting the anchor 300 into bone. Outer tube 404 and outer tube manipulator 406 (see FIGS. 7A and 7B) are positioned relative to inner tube 420 and handle 402 (see FIGS. 7 and 8) so that the outer tube 404 engages hex nut structure 106 in the anchor base 100. It is advantageous in this configuration for the anchor top 200 to be in a position relative to the anchor base 100 such as depicted in FIG. 6A. In the configuration of FIG. 9A, a surgeon may then screw the anchor base 100 into bone by twisting handle 402 of inserter 400 (see FIGS. 7A and 7B).

After the anchor base 100 is inserted into the bone, the outer tube 404 may be slid backward relative to the inner tube 420 and handle 402 to expose the anchor top 200 such as in FIG. 9B. One or more lengths of suture 600 may then be placed in the space between the distal surface 602 of the

US 7,585,311 B2

9

proximal member 204 of anchor top 200 and the proximal surface 604 of the anchor base 100 by moving the suture laterally into the space as depicted in FIG. 9C. The suture 600 may be manually tensioned as desired. In some embodiments, tensioning of the suture 600 is aided by pulling the suture 600 against the distal member 202 of the anchor top 200.

After appropriate tensioning of suture 600, wire manipulator 408 may be pressed to tension the wire, causing the handle 402 of the inserter 400 and the inner tube 420 to be pulled down towards the anchor base 100 so that inner tube 420 ratchets the anchor top 200 down into the anchor bottom 100 as depicted in FIG. 9D. As the anchor top 200 is pushed axially down, suture 600 will be clamped between the distal surface 602 of the proximal member 204 of anchor top 200 and the proximal surface 604 of the anchor base 100 (see also FIG. 9C). The clamping will force the suture to be compressed within the passageways 302 and 304 depicted in FIG. 6B and thus be secured to anchor 300. The fit between the anchor top 200 and the anchor base 100 in the clamping region is such that the suture 600 is firmly gripped, but is not cut, when it is clamped in place. Appropriate edges that may contact the suture are preferably beveled or rounded to avoid damage to the suture. After anchor top 200 is ratcheted sufficiently into anchor base 100, wire manipulator 408 (see FIGS. 7A and 7B) in inserter 400 may be compressed further to further tension wire 422 (see FIG. 8) such that wire 422 breaks free from its attachment to anchor base 100, thus leaving the anchor 300 free from inserter 400 with suture 600 securely attached as depicted in FIG. 9E.

Although a particular inserter device for inserting and manipulating anchor 300 has been described, it should be understood that other inserter designs may be used for manipulating the parts of anchor 300 described above to insert the anchor into bone and secure suture material to the anchor. For example, it may be possible to use separate tools for inserting the anchor and securing the suture material. In addition, in alternative embodiments, the anchor base 100 may be connected to the anchor top 200 throughout the procedure, or the anchor base may be separately inserted into the bone, and the anchor top can be attached thereafter by axially sliding the distal end of the anchor top 200 into the hole 108 in the anchor base 100.

It will be appreciated by those of skill in the art that the anchor 300 and inserter 400 provide a system for easy attachment of a suture to bone. The anchor 300 may be inserted into bone with minimal disruption of surrounding tissue. Only an access route having the diameter of the outer tube 404 and the anchor base 100 is required. Furthermore, the suture can be securely attached to the anchor 300 and tensioned as desired without having to insert additional instrumentation into the site or without performing any cumbersome attachment maneuvers such as knot tying. It should also be appreciated that the general principle illustrated by this system of inserting an anchor into bone without having suture material pre-attached and then attaching suture to the anchor without tying any knots may be implemented using any appropriate system other than the specific embodiments depicted in FIGS. 4-9.

#### Tissue and Bone Piercing Anchor

One embodiment is a bone anchor adapted for piercing through the soft tissue and into underlying bone. In one embodiment, the suture material may be pre-attached to the piercing bone anchor so that after implantation, a suture passes from the bone anchor through to the top of the soft tissue for easy passing over the soft tissue. In one embodiment, the piercing bone anchor has two configurations, a first configuration having a small diameter for easy piercing

10

through soft tissue and bone and a second deployed configuration where structures such as protrusions are deployed to prevent the bone anchor from being easily removed from the bone.

In one embodiment, the anchor includes a substantially hollow cylinder having a portion of its walls cut in such a manner so as to allow the cylinder to deform under axial stress and form lateral protrusions. The lateral protrusions may thus prevent the anchor from being easily removed from the bone after deployment. In one embodiment, the anchor comprises a pointed tip coupled to the hollow cylinder for piercing the soft tissue and bone. In one embodiment, suture is pre-attached to the pointed tip inside of the hollow cylinder. In other embodiments, suture is pre-attached at other locations on the piercing anchor, such as at the proximal end of the hollow cylinder.

One embodiment of a deployable piercing anchor is depicted in FIGS. 10A and 10B. In FIG. 10A, the anchor is depicted in a pre-deployed state. The anchor includes a substantially hollow cylinder 650 with a plurality of cuts 652 in the side of the cylinder 650. The cylinder 650 is open on one end 654. On the other end, a pointed tip 656 is disposed, allowing the anchor to pierce through soft tissue and bone. In FIG. 10B, the anchor is depicted in a deployed state. Stress is applied in an axial direction such that the cylinder 650 collapses along cuts 652 so as to form two lateral wings 660. The lateral wings 660 prevent the anchor from being removed from the bone. Hinges 662 connect one end of each wing to either the top or the bottom parts of anchor body. These hinges deform and fold, in the plane tangent to the anchor body at that point when the anchor is deployed. A strip of material 664 connects the top and bottom wing on each side of the anchor body, and serves as a hinge between the two as well as aiding in alignment of the wings during deformation. The tips of the wings adjacent to the connecting strip 664 utilize rolling edges 666, which ensure uniform alignment and smooth transition during deformation. Those of skill in the art will appreciate that any number of geometries of cuts in the cylinder 650 may be utilized to create a deformable structure that will produce lateral protrusions upon exposure to stress.

In some embodiments, structures may be positioned within the cylinder 650 for attaching sutures and engaging with an anchor inserter. In one embodiment, such structures are coupled to the anchor tip 656 within the cylinder 650. FIG. 11 depicts one such embodiment. Attached to the tip 656 is a structure 670 through which there is an aperture 672. The structure 670 may be adapted to engage the inner surface of cylinder 650 for attaching the tip 656 to the cylinder 650. The attachment mechanism may be by forced fit, frictional fit, threads, welding, adhesive, or any other suitable means. Suture material may be threaded through the aperture 672 in order to attach the suture to the anchor. The suture material may be secured to the tip 656 by tying the suture around structure 670, tying a knot in the end of the suture that prevents it from being pulled through the aperture 672, clamping the suture between the structure 670 and the inside of the cylinder 650, adhering the suture to structure 670 by welding or adhesive, or any other suitable means. In one embodiment, the suture material is attached to the anchor at tip 656 prior to use of the anchor.

An anchor inserter attachment structure 674 may also be coupled to the tip 656. This structure 674 may couple to an anchor inserter through a wire or any other suitable means. The attachment between the anchor inserter and the anchor at this point may be used to apply axial stress to the anchor for



## US 7,585,311 B2

11

deploying the anchor as described above. The attachment at this point may also serve to keep the anchor attached to the inserter prior to deployment.

One embodiment of an anchor inserter suitable for use with the above-described anchor is depicted in FIG. 12. The anchor inserter comprises a grasping handle 700 to which is attached an outer sleeve 702 which is fixed relative to the handle 700. The piercing anchor 704 is disposed at the end of the sleeve 702. A deployment lever 706 may be pressed by a user to deploy and detach the anchor 704 as described below. A safety switch 708 may be provided to prevent the anchor 704 from being deployed prematurely. A spool 710 may be provided at the proximal end of the handle 700 for holding excess suture. A lid 712 may be provided for gaining access to the inner components of the inserter.

FIG. 13 depicts the anchor 704 coupled to the inserter. As described above, the anchor 704 comprises a hollow cylinder 650 with cuts in the sides and a pointed tip 656. Furthermore, as depicted in FIG. 11, a suture receiving aperture 672 and an inserter attachment structure 674 are attached to the pointed tip 656 within the cylinder 650. The outer sleeve 702 of the inserter may fit over the open end 654 of the cylinder 650 or be flush with the open end 654. The outer sleeve 702 may thus hold the top part of the anchor 704 steady during insertion. In an alternative embodiment, the outer sleeve 702 may fit over the length of the cylinder 650 to prevent the cylinder 650 from deforming while it is being inserted into bone. In this alternative embodiment, the outer sleeve 702 may be retracted prior to deployment of the anchor. An inner tube 720 may be positioned within the outer sleeve 702 and the hollow cylinder 650 and contact the top surface of the anchor tip 656 (see FIG. 11). The inner tube 720 provides structural reinforcement of the anchor 704 and pushes against the tip of the anchor 704 while it is being driven into bone or tissue. The inner tube 720 may be fixed relative to the handle 712 and outer sleeve 702 during insertion, however, during deployment of the anchor 704, the inner tube 720 may be released by switching safety switch 708 so that the inner tube 720 can move axially relative to the outer sleeve 702 while the anchor cylinder 650 collapses. A wire may be positioned inside of the inner tube 720 running from within the handle 712 through the inner tube 720 to the anchor 704 and attached to the anchor inserter attachment structure 674. During deployment, the lever 704 may be pressed to pull the wire axially towards the handle 700. The axially movement of the wire forces the anchor 704 to press against outer sleeve 702 and stresses the cylinder 650, causing it to deform and deploy. During collapse of the cylinder 650, the inner tube 720 will also move in an axial direction toward the handle 700. Upon further stress on the wire, the wire may break free from the anchor inserter attachment structure 674, releasing the inserter from the anchor 704. Suture material may run from the inside of handle 700 through the inner tube 720 to attach to the anchor 704 through aperture 672 (see FIG. 11). Upon detachment of the anchor inserter from the anchor 704, the inserter may be withdrawn, leaving the inserted and deployed anchor with suture coming out of the open end 654 of the cylinder 650. The suture will still be coupled to the inserter through the inner tube 720, handle 700, and around spool 710. Those of skill in the art will appreciate other inserters and mechanisms that may be used to insert and deploy the piercing anchors described herein. For example, rather than axially stressing the anchor 704 by pulling the tip 656 in an proximal direction, the cylinder 650 may be pushed in a distal direction to deform the cylinder 650.

FIG. 14 is a cut-away view of the handle 700, showing the inner workings of the anchor inserter. The suture material attached to a piercing anchor at the tip of the inserter may pass

12

through the central bore of the inner tube 720 and through a bore 750 in the handle 700. The suture material may then pass through a hole 752 in the end of the handle 700 and be wrapped around the spool 710, which may be integral with the handle 700. The wire attached to the anchor inserter attachment structure 674 in the anchor may also pass through the central bore of the inner tube 720 and may then proceed around a pulley 754 and attach securely to the handle 700 at point 756. The pulley 754 may be attached to the lever 706. When the lever 706 is pressed down, the pulley 754 will move toward the back end of the handle 700, causing the wire attached to the anchor to retract. Because of the use of pulley 754, the wire will retract twice the distance as the pulley 754 moves.

The safety switch 708 may be used to prevent the lever 706 from being pressed and prevent the inner tube 720 from moving unless the safety switch 708 is in the correct position. The safety mechanism operates via a drum 760 disposed within the handle 700 to which the safety switch 708 is attached. Moving the safety switch 708 rotates the drum 760 within the handle 700. FIG. 15 shows the drum 760 and safety switch 708 mechanism in more detail. The inner tube 720 passes through a central bore in the drum 760. On the other side of the drum 760, the inner tube 720 is attached to a stopper 762. The stopper 762 has a through-hole 764 to permit passage of the deployment wire and suture. The stopper 762 may be positioned within a cavity 766 in the end of the drum 760. A second similarly shaped cavity may be disposed within the handle 700. The stopper 762 and attached inner tube 720 may only be allowed to move axially relative to the handle 700 when the safety switch 708 and drum 760 is rotated so that the cavity 766 in the drum 760 is aligned with the matching cavity in the handle 700. When the cavities are aligned, the stopper 762 is allowed to move from the cavity 766 to the cavity in the handle 700, thus allowing the inner tube 720 to move axially and the anchor to be deployed.

Additionally, the drum 760 comprises a groove 768. A spring-loaded sliding pin 770 (see FIG. 14) may be coupled to the lever 706. The lever 706 can only be moved when the drum 760 and switch 708 are rotated so that groove 768 is aligned with the pin 770. Thus, both the stopper 764 and the pin 770 prevent the anchor from being deployed unless the switch 708 is in the correct position.

Those of skill in the art will appreciate other mechanisms that could be used for deploying a deployable anchor and providing safety mechanisms to prevent premature deployment.

#### Example Using a Piercing Anchor and a Suture Capturing Anchor

The above-described anchors may be used in a surgical procedure for attaching soft tissue to bone. One example of such a procedure is depicted in FIGS. 16A through 16F. In FIG. 16A, the piercing anchor 800 attached to an anchor inserter 802 as described above is pierced through soft tissue 804 that has become detached from underlying bone 806. In FIG. 16B, the anchor inserter 802 is moved laterally relative to the bone 806 so as to stretch the soft tissue 804 laterally relative to the bone 806. Once the soft tissue 804 has been stretched to the desired position, the anchor 800 is inserted into the bone 806 and the anchor 800 is deployed as described above and the inserter 802 is detached from the anchor 800, leaving a suture 808 attached to the anchor 800 and extending through the soft tissue 804. The anchor 800 may be inserted into bone 806 by tapping on the inserter 802 with a hammer or by any other suitable means of applying axial force. FIG. 16C

US 7,585,311 B2

13

depicts the deployed anchor 800 with attached suture 808. The suture 808 will extend into the inserter 802.

Next, as depicted in FIG. 16D, a suture capturing anchor 810 is inserted into the bone 806 using the inserter 812 as described above. In FIG. 16E, the inserter 812 is then retracted to expose the suture capturing mechanism. The suture 808 is then passed over the soft tissue 804 and laterally moved into the suture capturing mechanism and tensioned. Finally, as depicted in FIG. 16F, the suture capturing mechanism is deployed to capture the suture 808, the anchor inserter 812 is detached from the anchor 810, and the suture 808 is cut to detach it from the suture inserter 802. The result is a length of suture 808 between the bone anchors 808 and 810 that presses the soft tissue 804 against the bone 806. Multiple anchors and sutures may be used to produce geometries such as depicted in FIGS. 2 and 3 and variations thereof.

It will be appreciated that there are numerous stitches, suture threading patterns, and anchor patterns that may be used to secure soft tissue to bone by the methods and devices described herein. These variations as well as variations in the design of the above described anchor devices and inserter devices are within the scope of the present disclosure.

#### Methods of Attaching Soft Tissue to Bone

Various embodiments include methods for attaching soft tissue to bone. In some embodiments, the methods include using the bone anchors described above. In one embodiment, a bone anchor is inserted into the bone and then a length of suture is passed over the soft tissue and secured to the anchor after inserting the anchor without tying any knots or without passing the suture through an aperture in the anchor. In some embodiments, the suture is secured to the anchor by laterally moving it into a securing mechanism. In one embodiment, securing the suture to the anchor includes clamping the suture between at least two surfaces on the anchor. In one embodiment, the anchor is not inserted further into the bone after securing the suture to it.

In another embodiment, a first anchor with a suture pre-attached is inserted through the soft tissue and into the bone. The suture may then be passed over the soft tissue and fixedly secured to a second bone anchor. In one embodiment, the first anchor is inserted by directly piercing the soft tissue and the bone. In one embodiment, lateral protrusion may be deployed on the first anchor to prevent the first anchor from being removed. In one embodiment, the suture may be coupled to the second bone anchor prior to insertion and then fixedly secured after insertion. In this context, "coupled" means that the suture is attached to the bone anchor but not fixedly secured, such that the suture can move to some extent relative to the bone anchor. In an alternative embodiment, the suture is not coupled to the second bone anchor during its insertion.

In another embodiment, a first portion of suture is inserted into the proximal surface of the soft tissue. A second portion of the suture (e.g., the portion proximal to the inserted portion) is then passed over the proximal surface of the soft tissue and fixedly secured to a bone anchor. In one embodiment, the procedure may be performed without passing the first portion of the suture back out of the proximal surface of the soft tissue. In one embodiment, this result is accomplished by the first portion of the suture being attached to an anchor that is inserted through the soft tissue and into bone.

One embodiment includes inserting a first anchor with a pre-coupled suture through soft tissue and into bone. The suture may then be passed over the soft tissue and fixedly secured to a second anchor. In one embodiment, the pre-coupled suture is fixedly secured to the first anchor prior to insertion. In an alternative embodiment, the pre-coupled

14

suture can move relative to the first anchor prior to insertion and is fixedly secured after insertion.

In another embodiment, multiple lengths of suture are attached to multiple anchors. In one embodiment at least three anchors are inserted into bone. A first length of suture may be secured between a first and second anchor and a second length of suture may be secured between the first and a third anchor. In one embodiment, the first anchor is positioned beneath the soft tissue and the second and third anchors are positioned laterally to the soft tissue. In an alternative embodiment, the first anchor is positioned laterally to the soft tissue and the second and third anchors are positioned beneath the soft tissue. In some embodiments, the lengths of suture are fixedly secured to the anchor(s) positioned beneath the soft tissue prior to insertion of those anchor(s). In one embodiment, the different lengths of suture may be tensioned separately.

In various embodiments, prior to fixedly securing suture to a bone anchor, it can be tensioned. In one embodiment, tensioning is accomplished by manually pulling on the suture such as by a surgeon grasping the suture using an appropriate instrument and then pulling. In one embodiment, the suture may be pressed against the bone anchor to provide leverage for pulling. For example, the suture may be wrapped partly around a proximal portion of the anchor prior to pulling.

Although the invention has been described with reference to embodiments and examples, it should be understood that numerous and various modifications can be made without departing from the spirit of the invention. Accordingly, the invention is limited only by the following claims.

What is claimed is:

1. A method of attaching soft tissue to bone, comprising: inserting a first anchor into bone, wherein the first anchor is positioned underneath the soft tissue such that no part of the anchor extends beyond an edge of the soft tissue; passing a first length of suture from said first anchor over the soft tissue; inserting a second anchor into bone, wherein the second anchor is positioned beyond the edge of the soft tissue such that it is not underneath the soft tissue; after inserting the second anchor, tensioning the first length of suture to compress an area of tissue to bone between the edge of the soft tissue and the first anchor; and fixedly securing the first length of suture to the second anchor without tying any knots.
2. The method of claim 1, wherein the first length of suture is fixedly secured to the first anchor prior to insertion of the first anchor.
3. The method of claim 1, wherein the first anchor is inserted through the soft tissue.
4. The method of claim 1, wherein the first length of suture is fixedly secured to the second anchor without passing the first length of suture through any aperture in the second anchor.
5. The method of claim 1, comprising inserting a third anchor into bone, wherein the third anchor is positioned beyond an edge of the soft tissue such that it is not underneath the soft tissue.
6. The method of claim 5, comprising passing a second length of suture from said first anchor over the soft tissue.
7. The method of claim 6, comprising fixedly securing the second length of suture to the third anchor without tying any knots.
8. The method of claim 1, wherein the first length of suture is coupled to the first anchor prior to insertion of the first anchor.



US 7,585,311 B2

15

9. The method of claim 8, wherein the first length of suture is fixedly secured to the first anchor after insertion of the first anchor.

10. The method of claim 1, wherein the first length of suture is coupled to the second anchor prior to insertion of the anchor.

11. The method of claim 1, comprising inserting a third anchor into bone, wherein the third anchor is positioned underneath the soft tissue at a location distinct from the first anchor.

12. The method of claim 11, comprising passing a second length of suture from said third anchor over the soft tissue.

13. The method of claim 12, wherein the second length of suture is crossed over the first length of suture.

14. The method of claim 12, comprising fixedly securing the second length of suture to the second anchor without tying any knots.

15. The method of claim 14, comprising inserting a fourth anchor into bone, wherein the fourth anchor is positioned beyond an edge of the soft tissue such that it is not underneath the soft tissue at a location distinct from the second anchor.

16. The method of claim 15, comprising passing a third length of suture from said third anchor over the soft tissue and the first length of suture.

17. The method of claim 16, comprising fixedly securing the third length of suture to the fourth anchor.

18. The method of claim 17, comprising passing a fourth length of suture from said first anchor over the soft tissue.

19. The method of claim 18, comprising fixedly securing the fourth length of suture to the fourth anchor.

20. The method of claim 1, comprising:

inserting a third anchor into bone, wherein the third anchor is positioned underneath the soft tissue at a location distinct from the first anchor;

inserting a fourth anchor into bone, wherein the fourth anchor is positioned beyond an edge of the soft tissue such that it is not underneath the soft tissue at a location distinct from the second anchor;

16

passing a second length of suture from said third anchor over the soft tissue and the first length of suture; and fixedly securing the second length of suture to said fourth anchor.

21. The method of claim 1, wherein inserting the first anchor into the bone comprises directly piercing the bone with the first anchor without drilling any holes.

22. The method of claim 1, wherein inserting the first anchor into the bone comprises deploying lateral protrusions on the first anchor, wherein the lateral protrusions are adapted to prevent the first anchor from being removed.

23. The method of claim 1, wherein the passing step comprises passing the length of suture over the soft tissue without the suture being coupled to the second anchor.

24. The method of claim 1, wherein suture is coupled to the second anchor prior to insertion and wherein, after inserting the second anchor, the length of suture is tensioned and then fixedly secured to the second anchor.

25. The method of claim 1, wherein the step of inserting the second anchor comprises inserting the anchor directly into the bone without the anchor passing through the soft tissue.

26. The method of claim 1, wherein no suture is coupled to the second anchor during its insertion and wherein, after inserting the second anchor, the length of suture is tensioned and then fixedly secured to the second anchor.

27. The method of claim 1, wherein the step of fixedly securing is performed without passing the suture through any apertures in the second anchor.

28. The method of claim 1, wherein the inserting steps, passing step, and fixedly securing step are conducted arthroscopically.

29. The method of claim 1, wherein passing the first length of suture over the soft tissue comprises passing the first length of suture over the edge of the soft tissue.

30. The method of claim 1, wherein the first length of suture passes through the soft tissue only once.

\* \* \* \* \*

UNITED STATES PATENT AND TRADEMARK OFFICE

**CERTIFICATE OF CORRECTION**

PATENT NO. : 7,585,311 B2  
APPLICATION NO. : 11/143007  
DATED : September 8, 2009  
INVENTOR(S) : Green et al.

Page 1 of 1

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

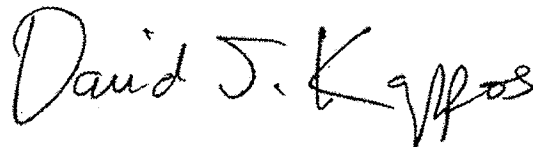
On the Title Page:

The first or sole Notice should read --

Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1126 days.

Signed and Sealed this

Fourteenth Day of September, 2010

A handwritten signature in black ink, reading "David J. Kappos". The signature is written in a cursive, flowing style.

David J. Kappos  
*Director of the United States Patent and Trademark Office*

# **EXHIBIT 2**



US008100942B1

(12) **United States Patent**  
**Green et al.**

(10) **Patent No.:** **US 8,100,942 B1**  
(45) **Date of Patent:** **\*Jan. 24, 2012**

(54) **SYSTEM AND METHOD FOR ATTACHING  
SOFT TISSUE TO BONE**

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(\*) Notice: Subject to any disclaimer, the term of this  
patent is extended or adjusted under 35  
U.S.C. 154(b) by 0 days.

This patent is subject to a terminal dis-  
claimer.

(21) Appl. No.: **13/245,620**

(22) Filed: **Sep. 26, 2011**

#### Related U.S. Application Data

(60) Continuation of application No. 12/549,105, filed on  
Aug. 27, 2009, which is a division of application No.  
11/143,007, filed on Jun. 1, 2005, now Pat. No.  
7,585,311.

(60) Provisional application No. 60/576,477, filed on Jun.  
2, 2004, provisional application No. 60/610,924, filed  
on Sep. 17, 2004, provisional application No.  
60/634,174, filed on Dec. 7, 2004.

(51) **Int. Cl.**  
**A61B 17/04** (2006.01)

(52) **U.S. Cl.** ..... **606/232; 606/300**

(58) **Field of Classification Search** ..... **606/72,**  
**606/75, 78, 219, 224, 232, 300-331**

See application file for complete search history.

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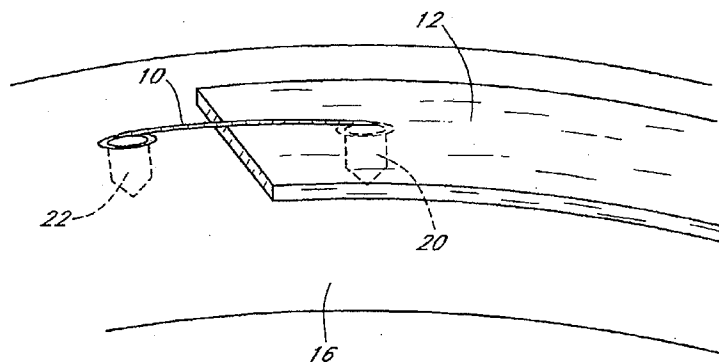
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(57) **ABSTRACT**

Disclosed herein are methods and devices for securing soft  
tissue to a rigid material such as bone. A bone anchor is  
described that comprises a base and a top such that suture  
material may be compressed between surfaces on the base  
and top to secure the suture to the anchor. Also described is an  
insert that can be used to insert the bone anchor into bone  
and move the anchor top relative to the anchor base to clamp  
suture material there between. Also described is a soft-tissue  
and bone piercing anchor and associated inserter. Methods  
are described that allow use of the bone anchors to provide  
multiple lengths of suture material to compress a large area of  
soft tissue against bone.

**19 Claims, 24 Drawing Sheets**



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Jan. 24, 2012

Sheet 1 of 24

US 8,100,942 B1

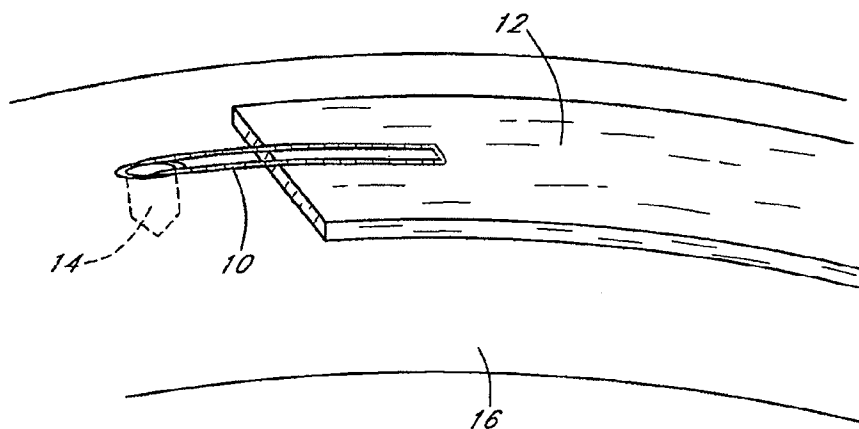


FIG. 1

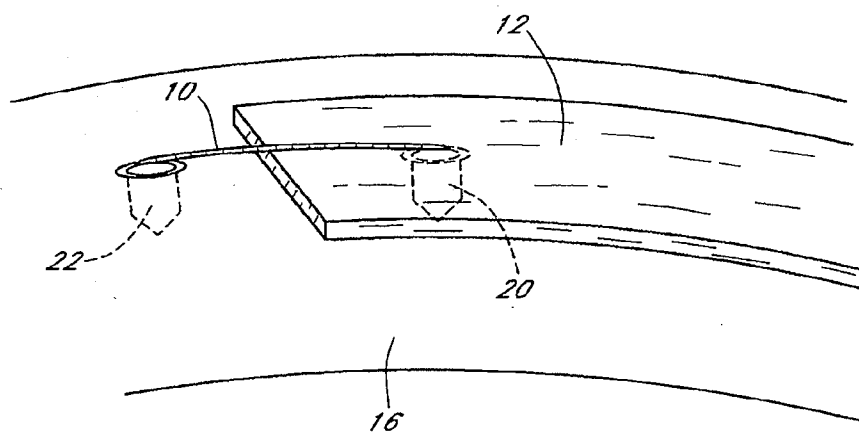


FIG. 2

U.S. Patent

Jan. 24, 2012

Sheet 2 of 24

US 8,100,942 B1

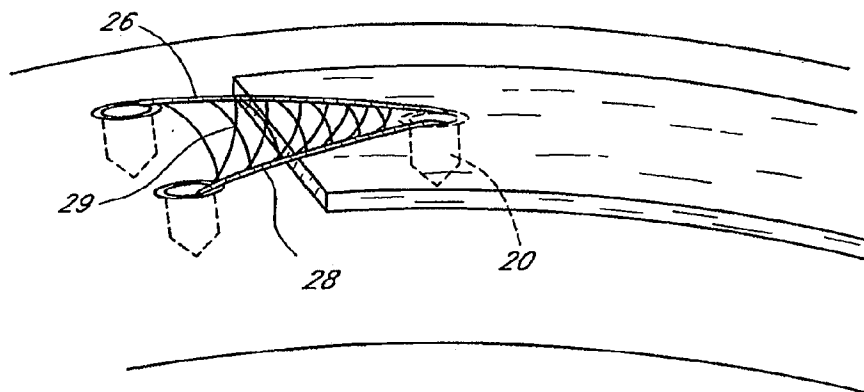


FIG. 3A

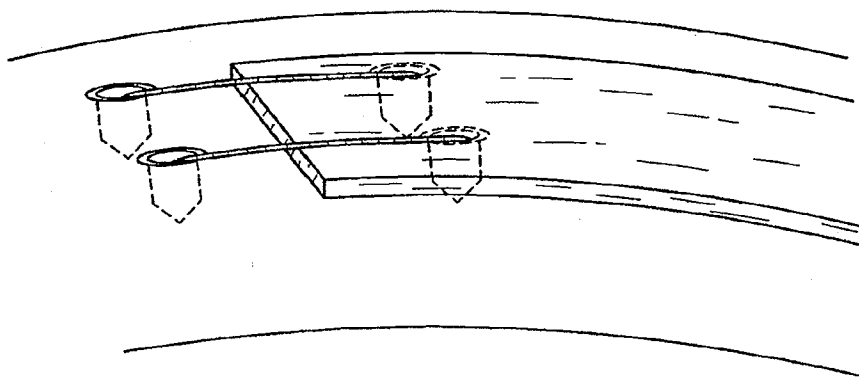


FIG. 3B

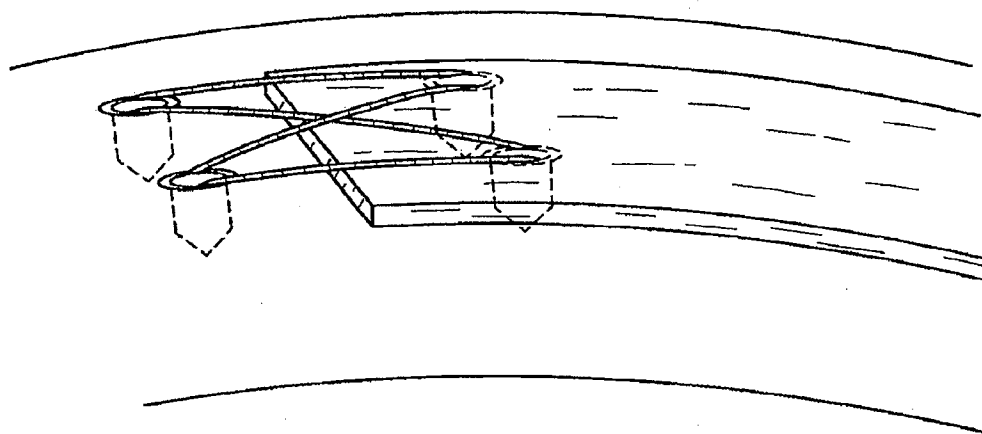


**U.S. Patent**

**Jan. 24, 2012**

**Sheet 3 of 24**

**US 8,100,942 B1**



**FIG. 3C**

U.S. Patent

Jan. 24, 2012

Sheet 4 of 24

US 8,100,942 B1

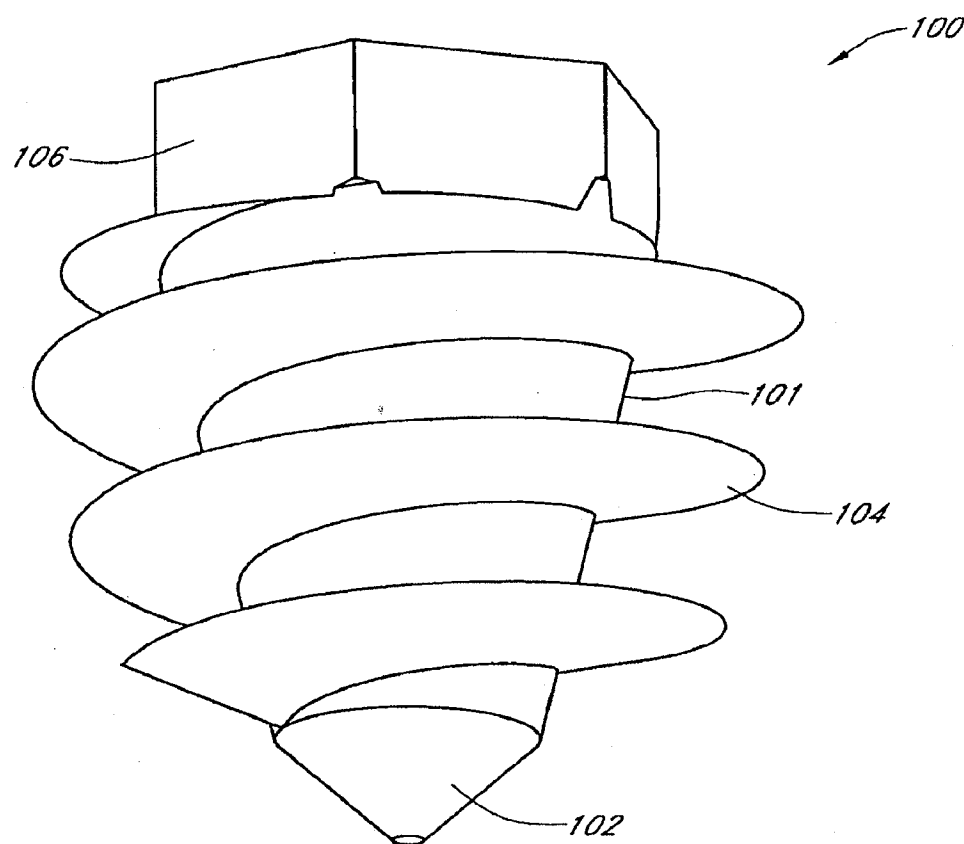


FIG. 4A

U.S. Patent

Jan. 24, 2012

Sheet 5 of 24

US 8,100,942 B1

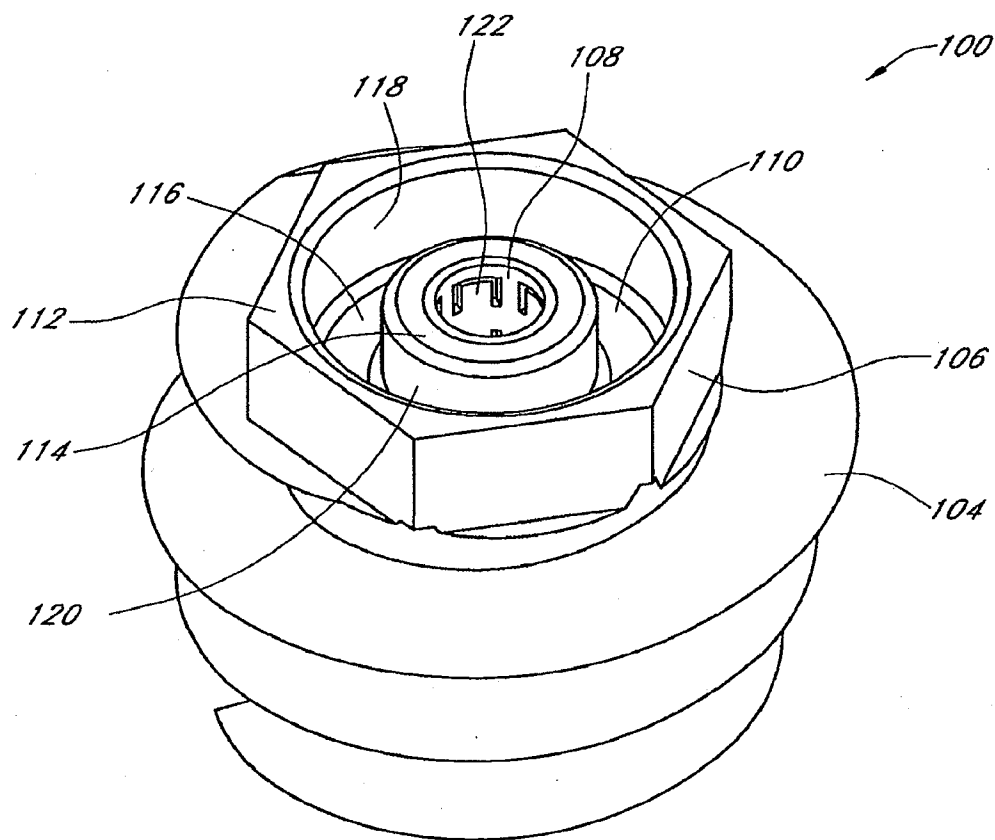


FIG. 4B

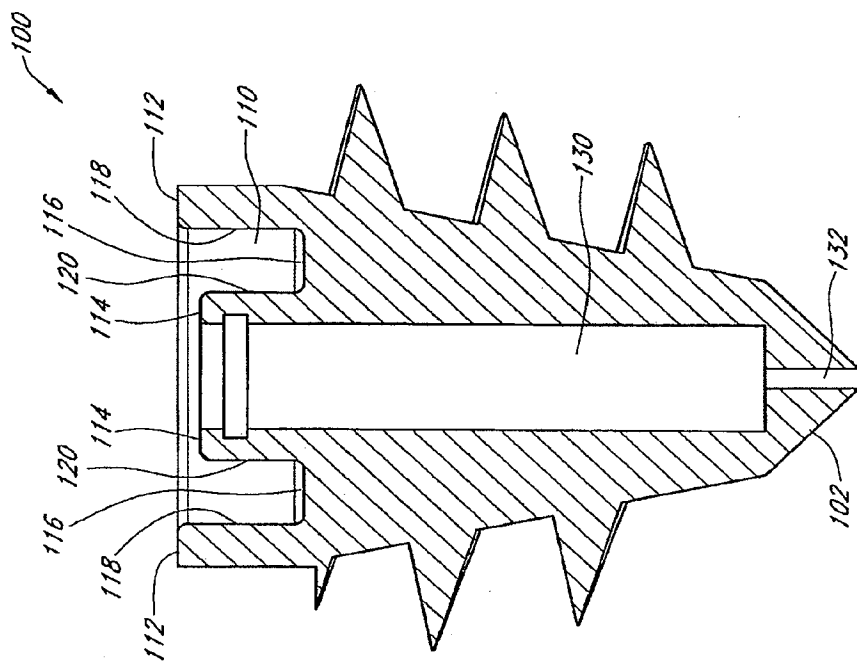


FIG. 4D

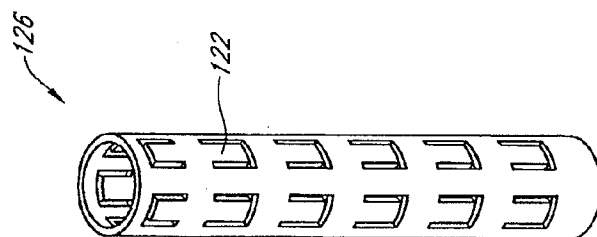


FIG. 4C

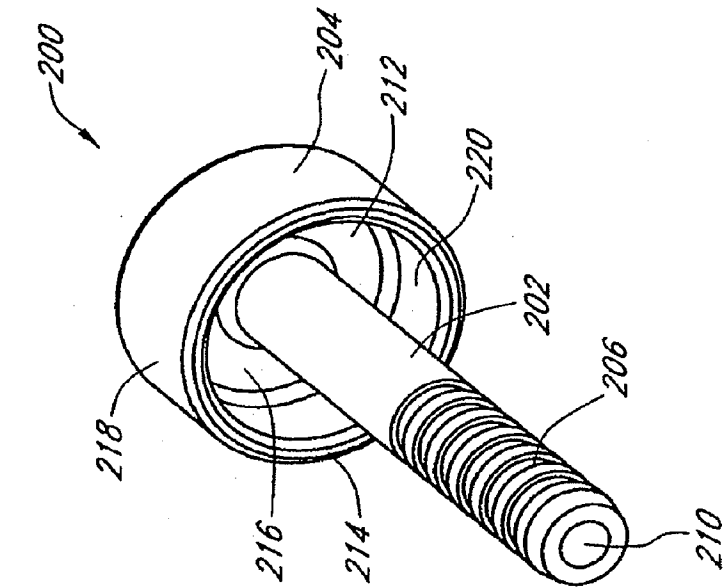


FIG. 5B

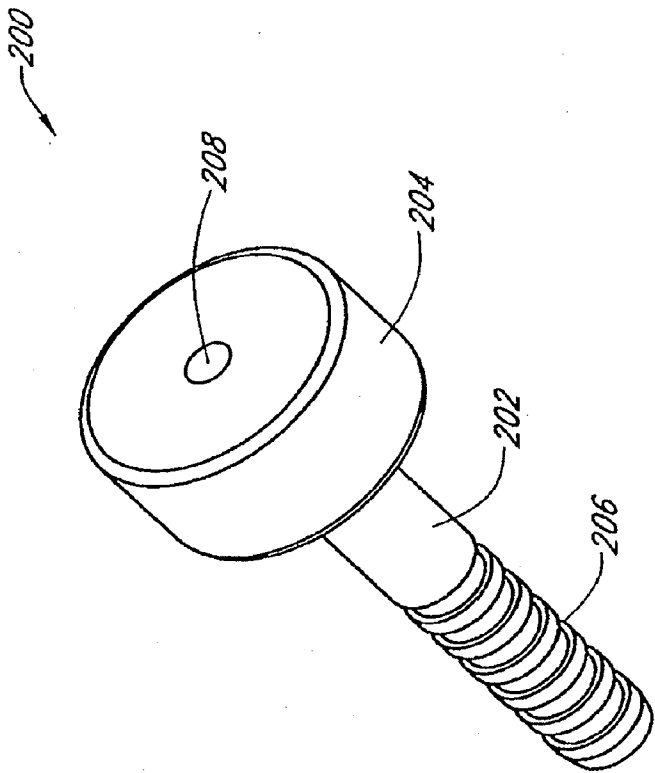


FIG. 5A

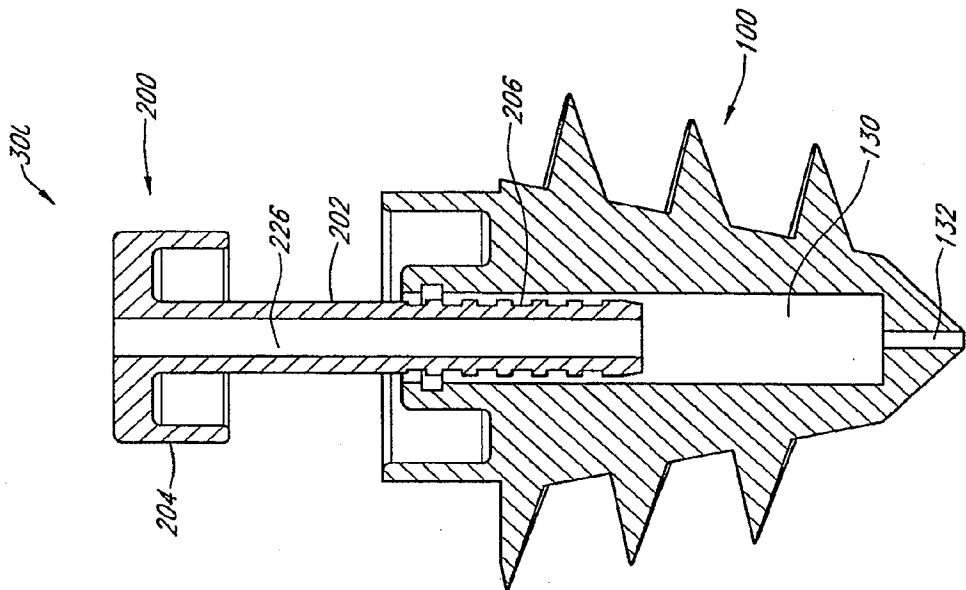


FIG. 6A

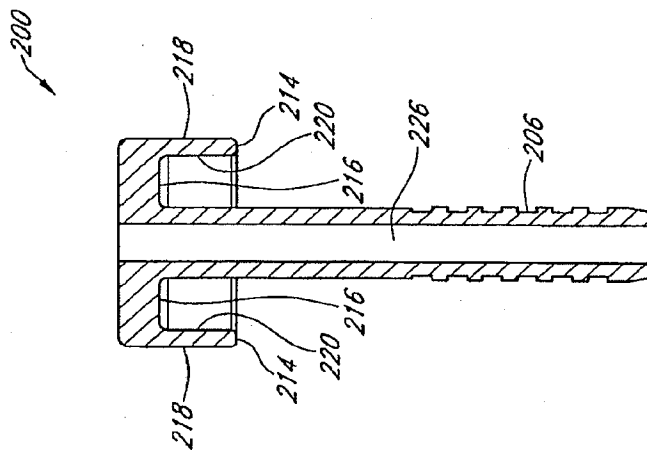


FIG. 5C

U.S. Patent

Jan. 24, 2012

Sheet 9 of 24

US 8,100,942 B1

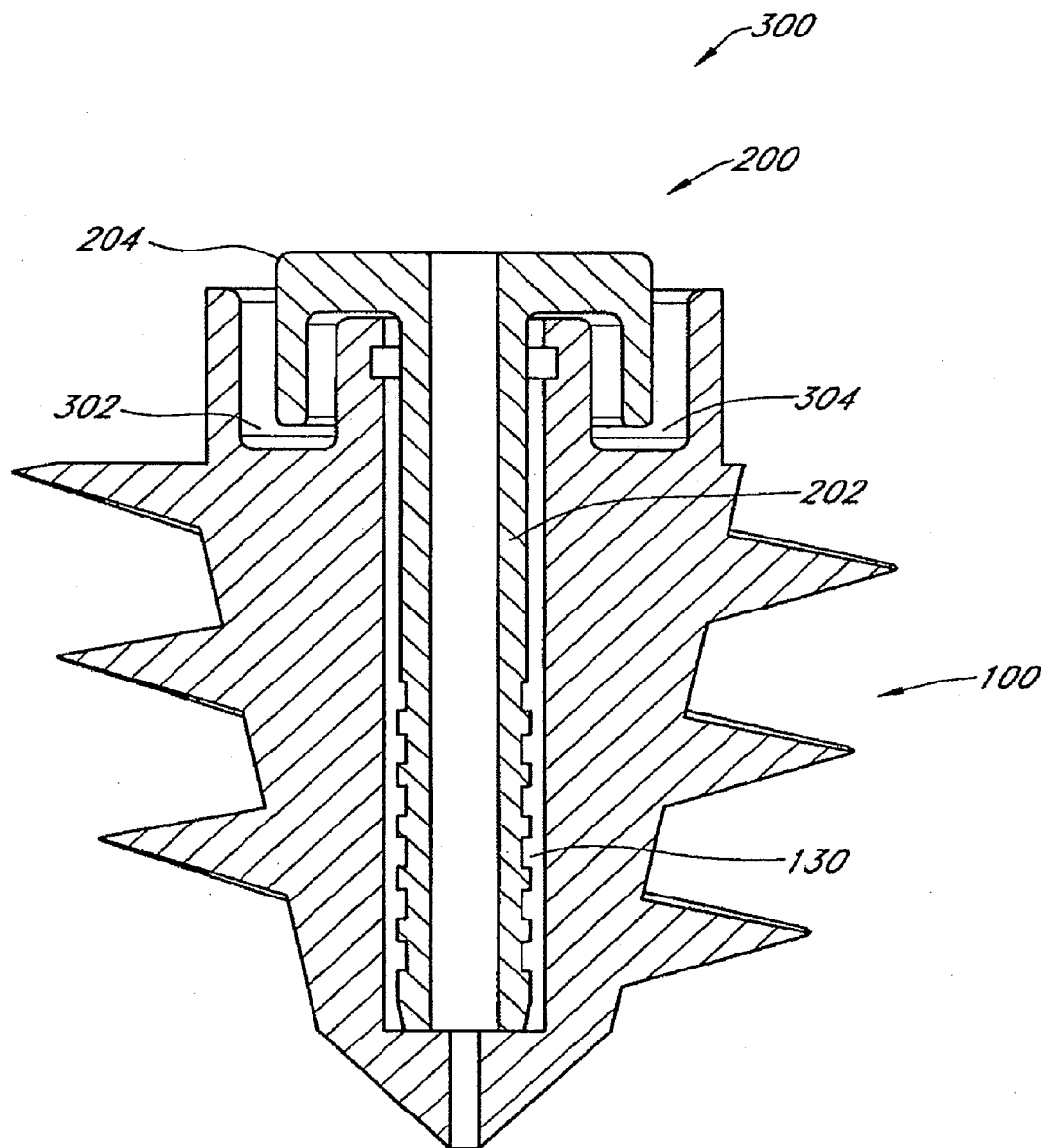
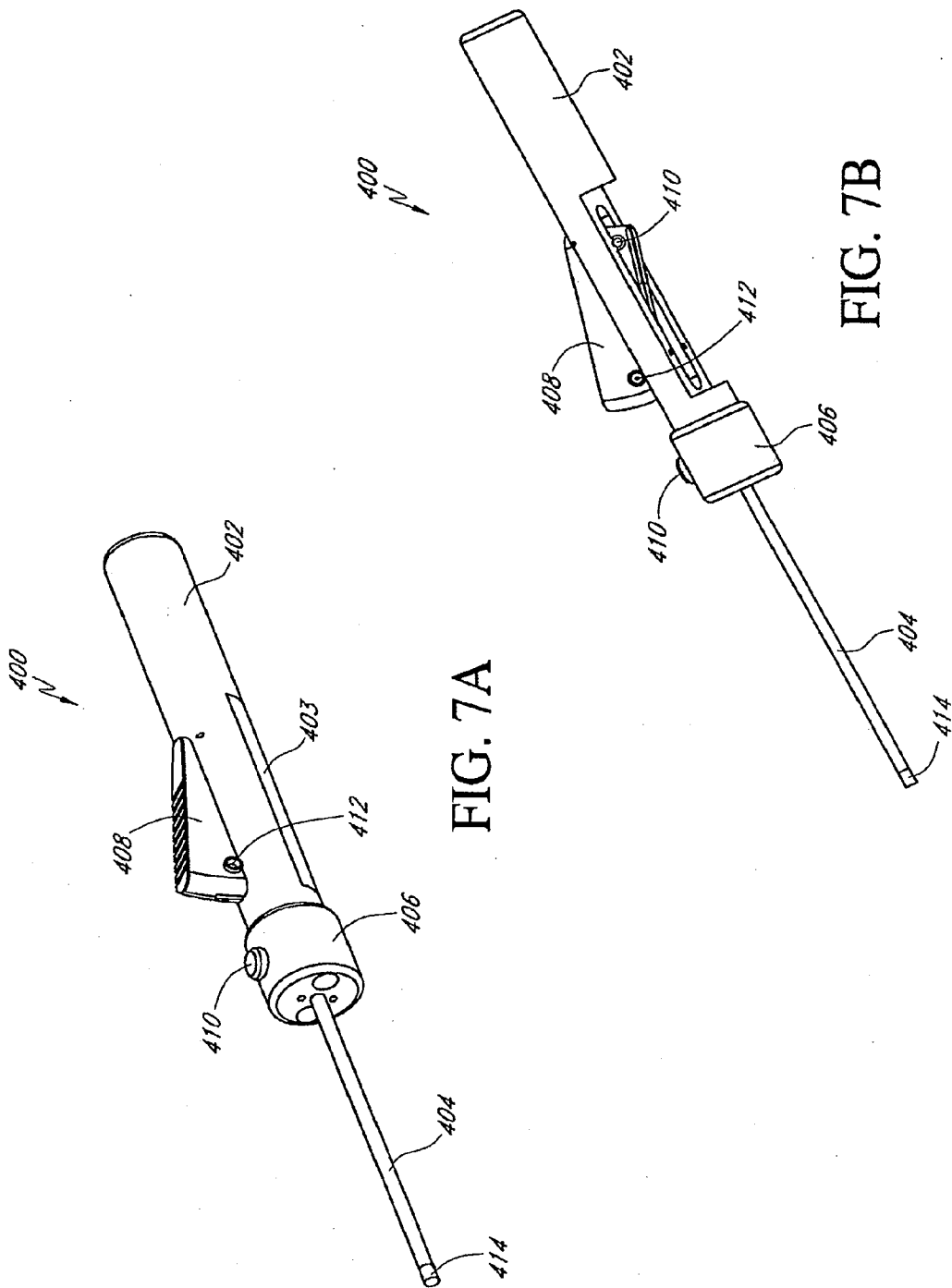


FIG. 6B





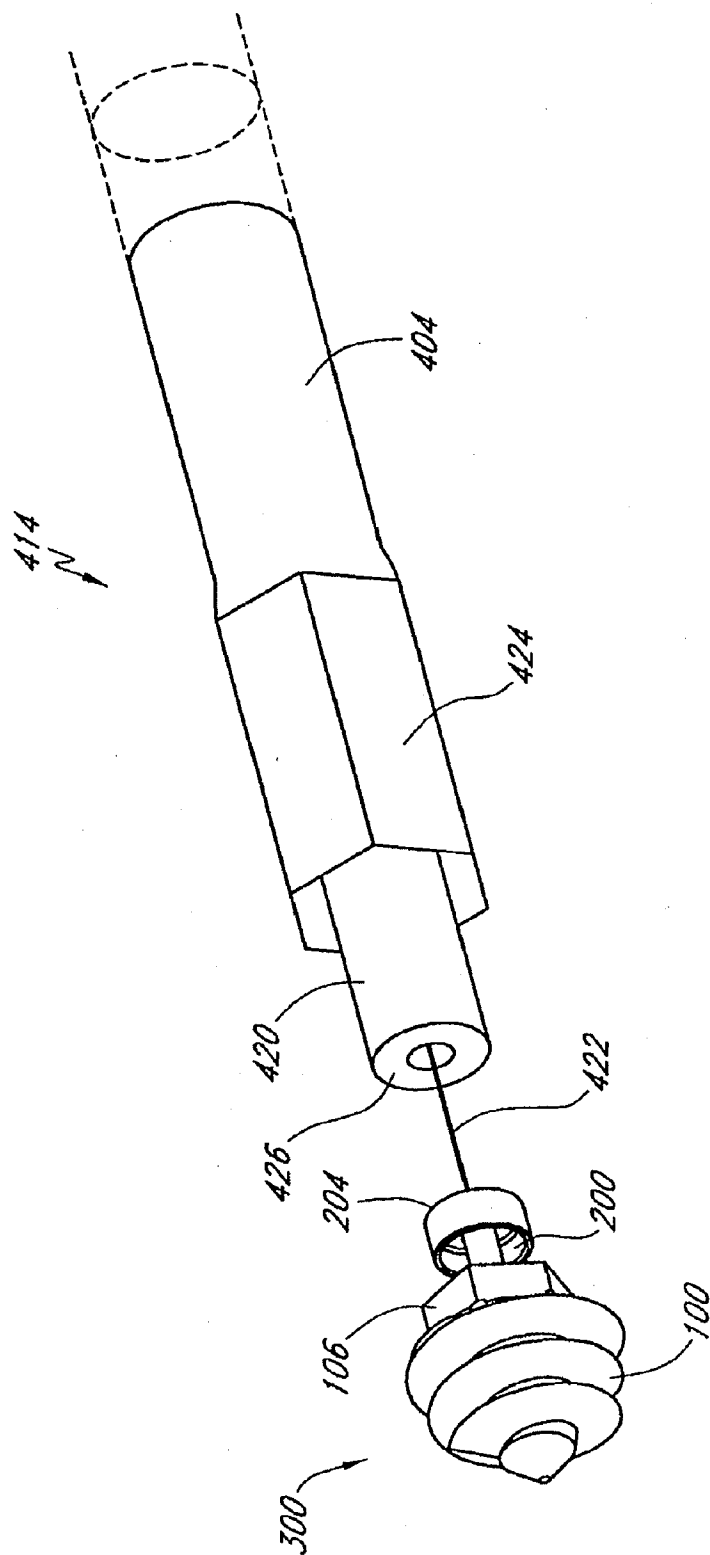


FIG. 8

U.S. Patent

Jan. 24, 2012

Sheet 12 of 24

US 8,100,942 B1

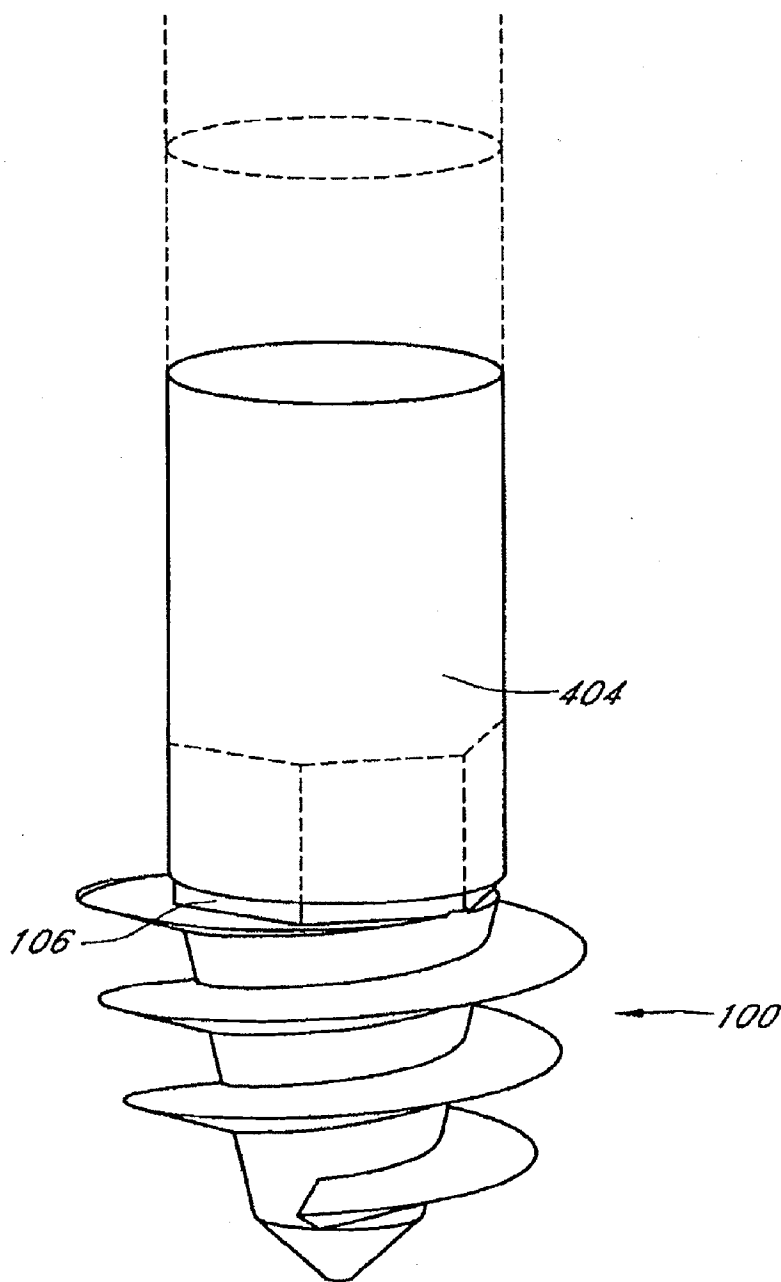


FIG. 9A

U.S. Patent

Jan. 24, 2012

Sheet 13 of 24

US 8,100,942 B1

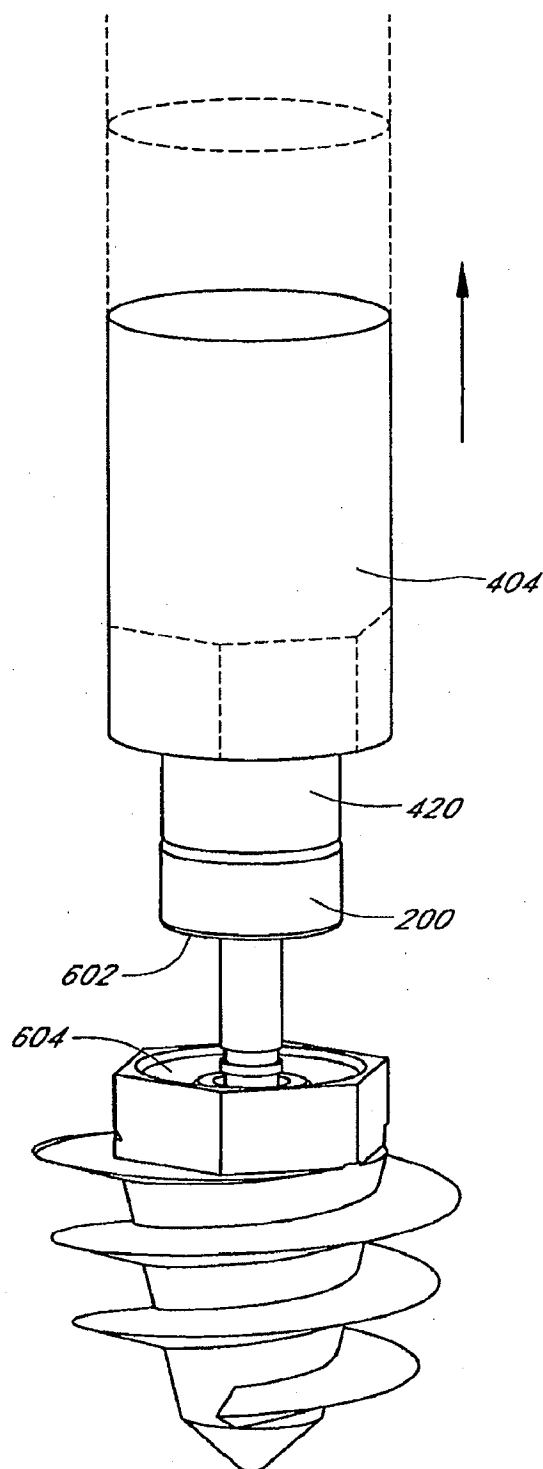


FIG. 9B

U.S. Patent

Jan. 24, 2012

Sheet 14 of 24

US 8,100,942 B1

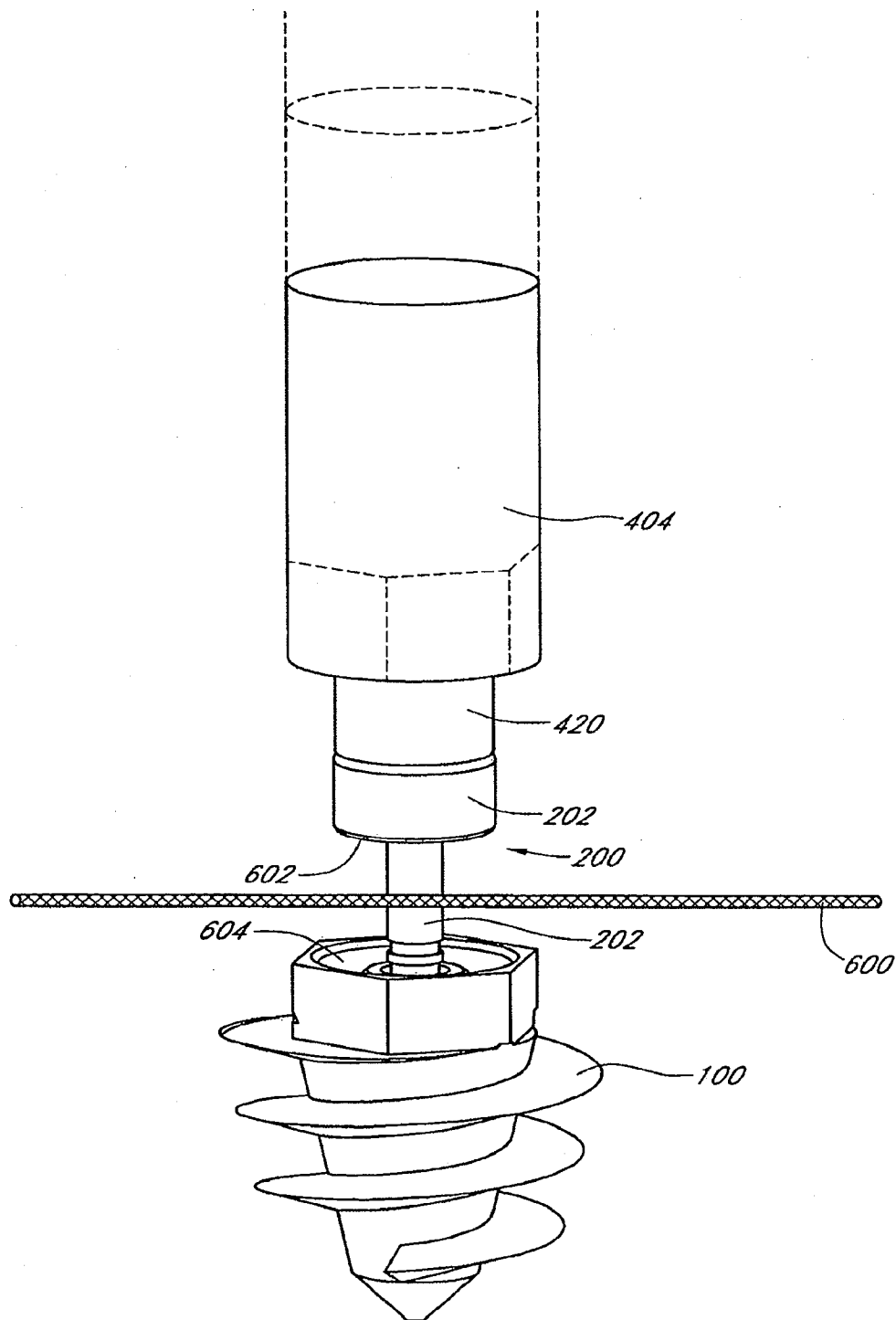


FIG. 9C

U.S. Patent

Jan. 24, 2012

Sheet 15 of 24

US 8,100,942 B1

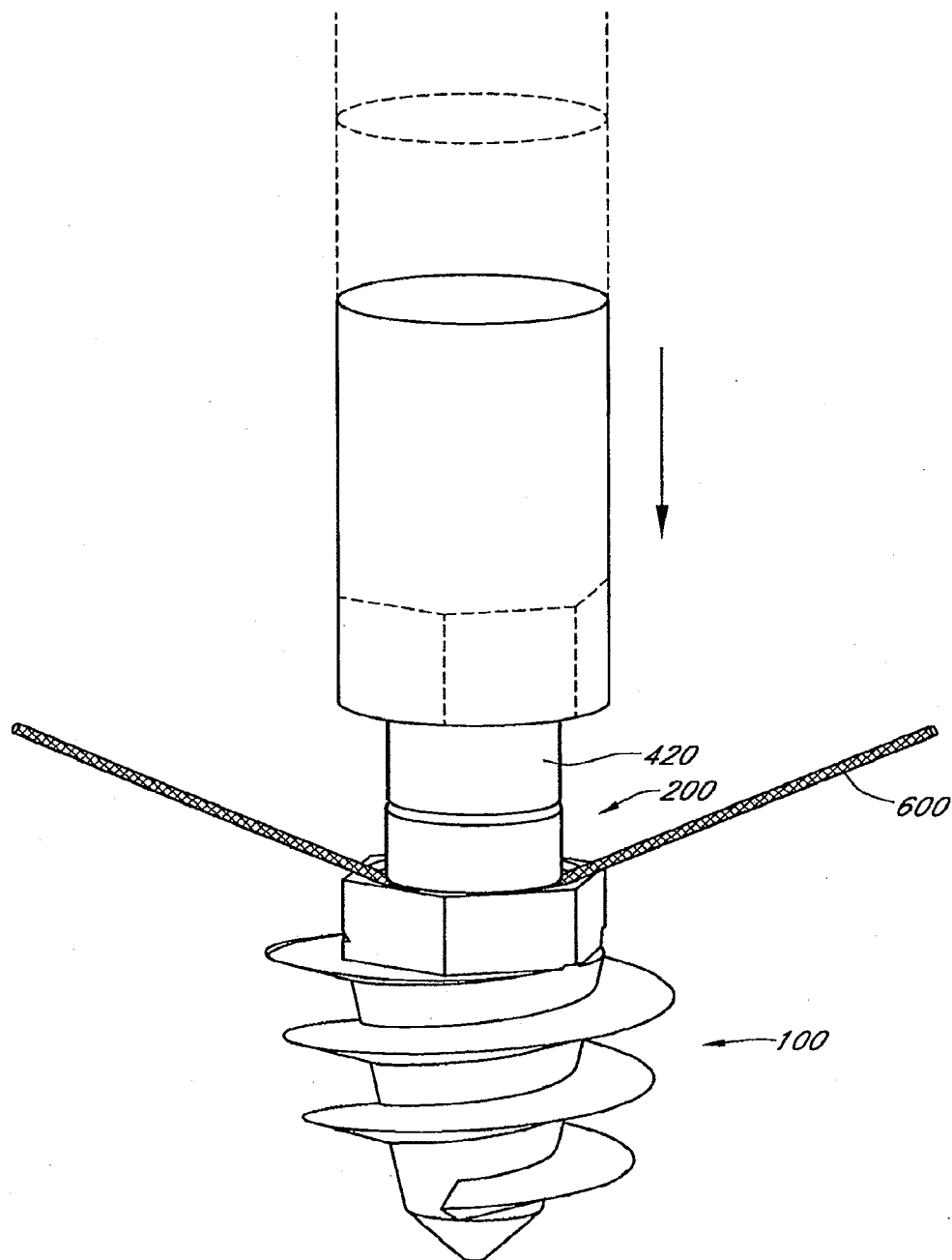


FIG. 9D

U.S. Patent

Jan. 24, 2012

Sheet 16 of 24

US 8,100,942 B1

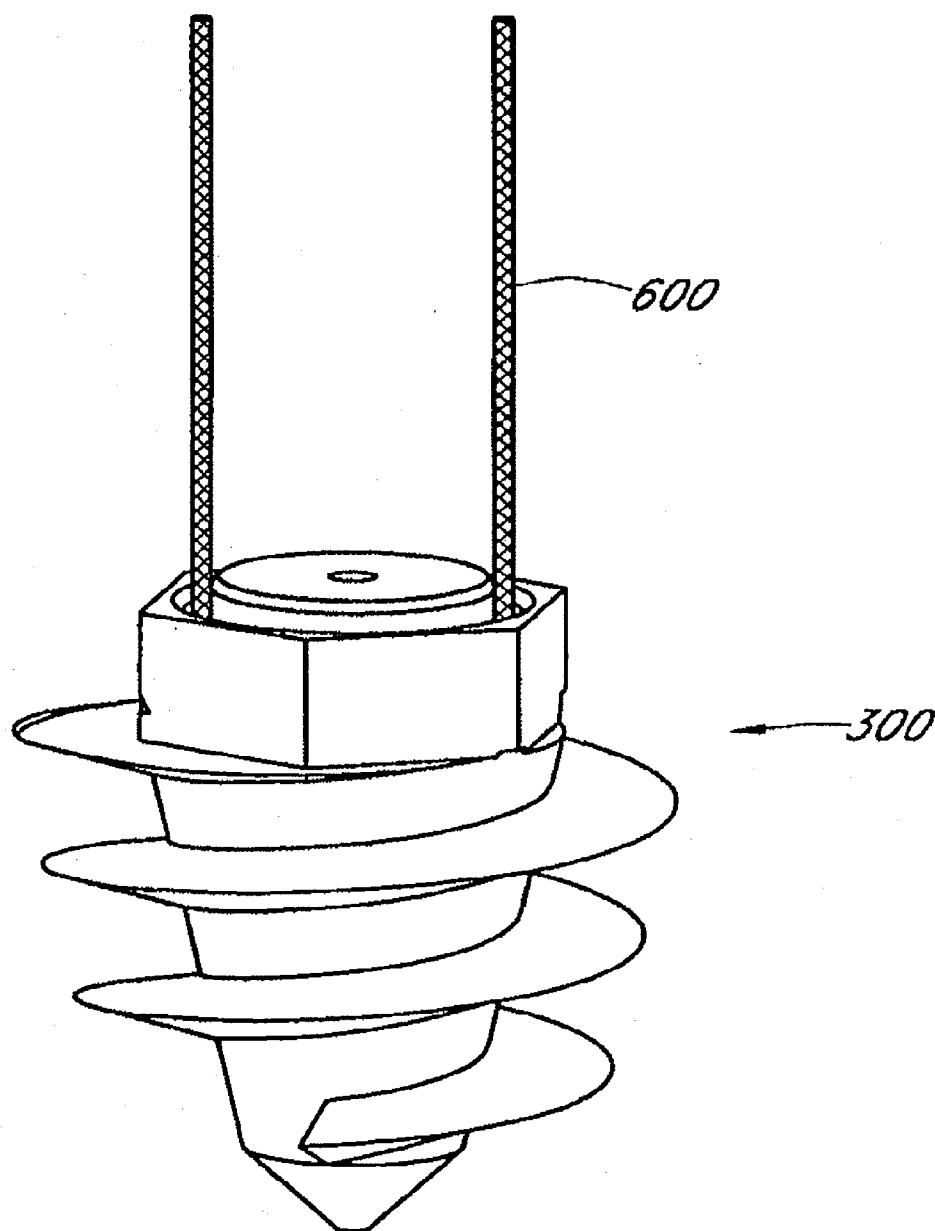


FIG. 9E

U.S. Patent

Jan. 24, 2012

Sheet 17 of 24

US 8,100,942 B1

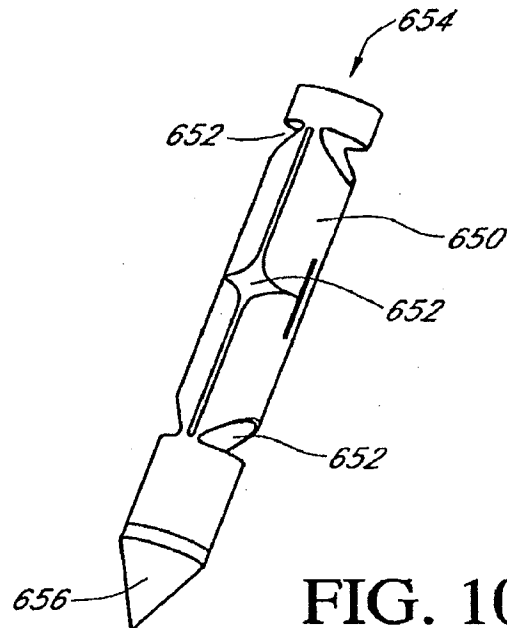


FIG. 10A

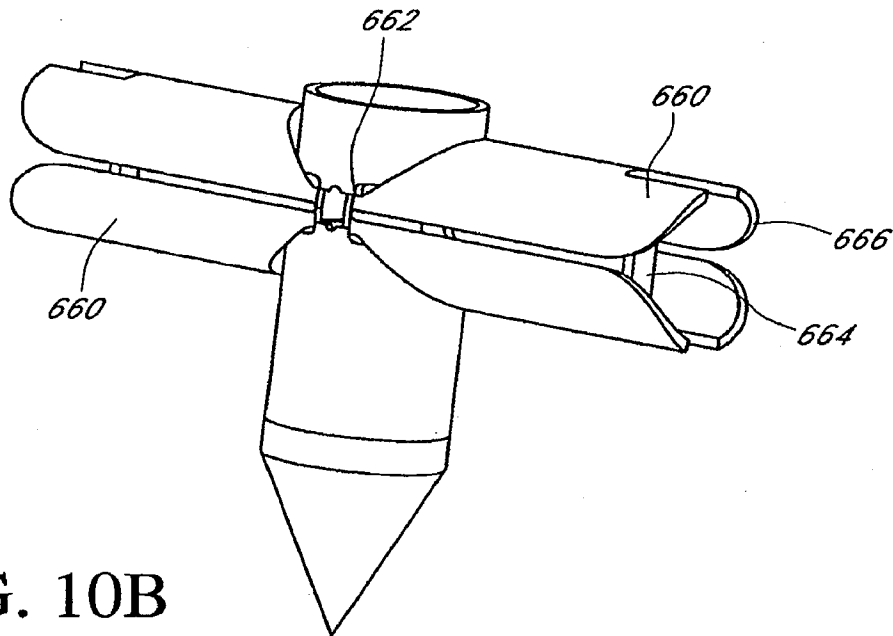


FIG. 10B

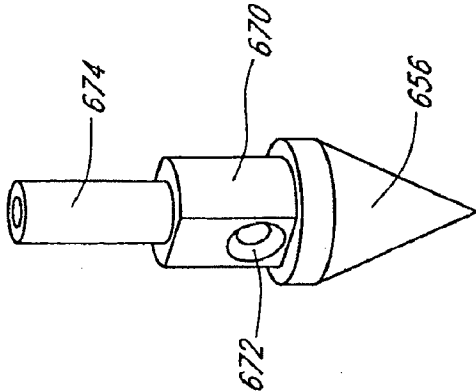


FIG. 11

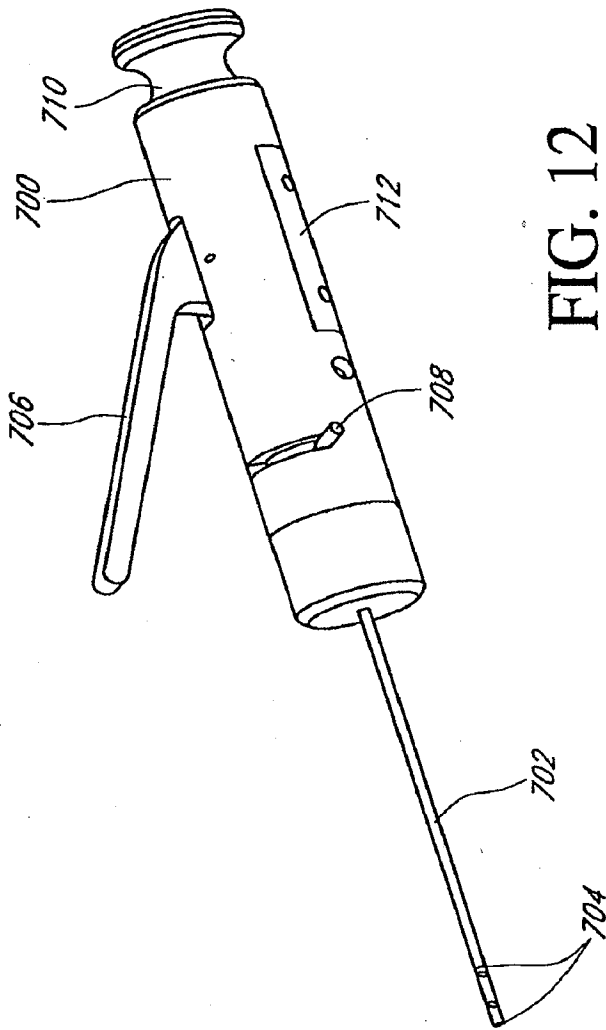


FIG. 12



U.S. Patent

Jan. 24, 2012

Sheet 19 of 24

US 8,100,942 B1

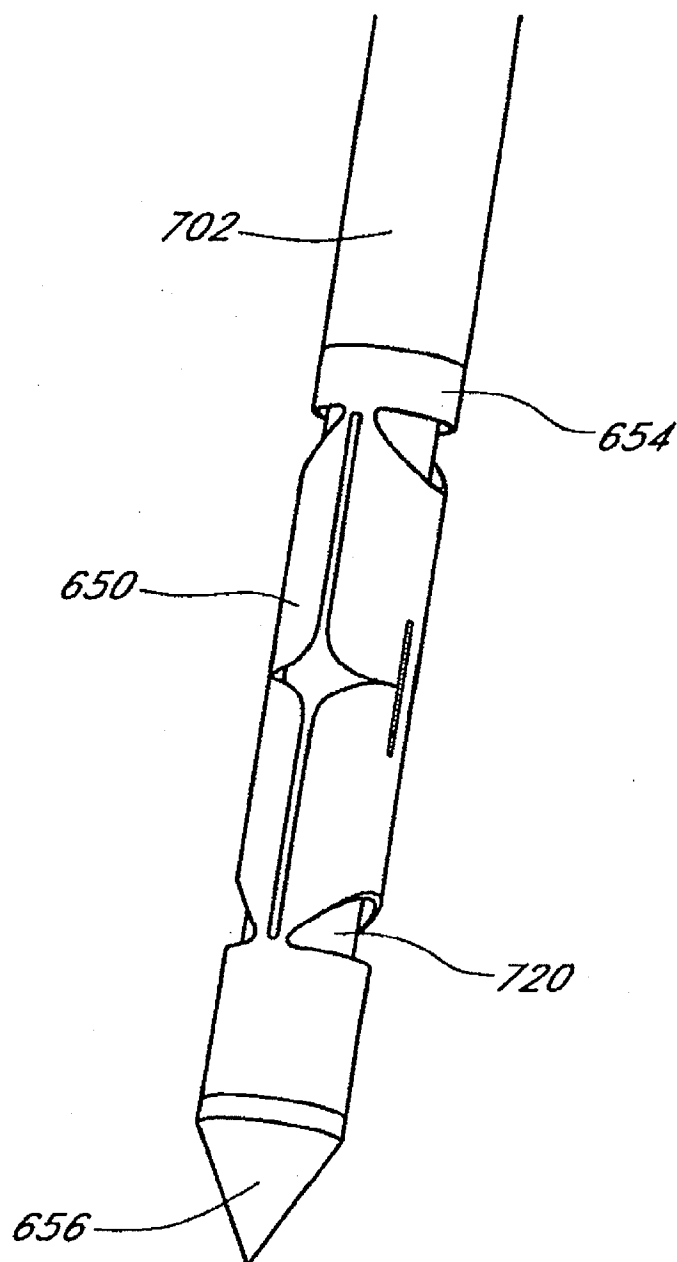


FIG. 13

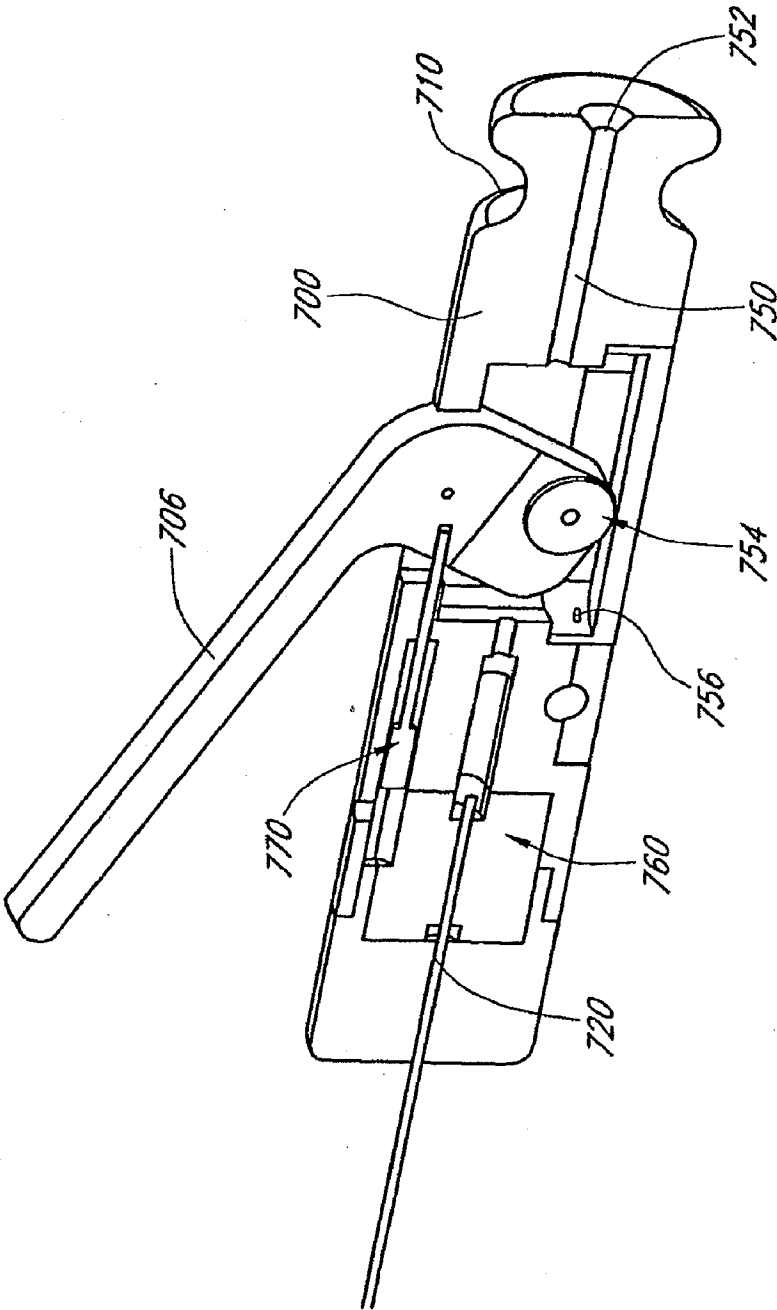


FIG. 14

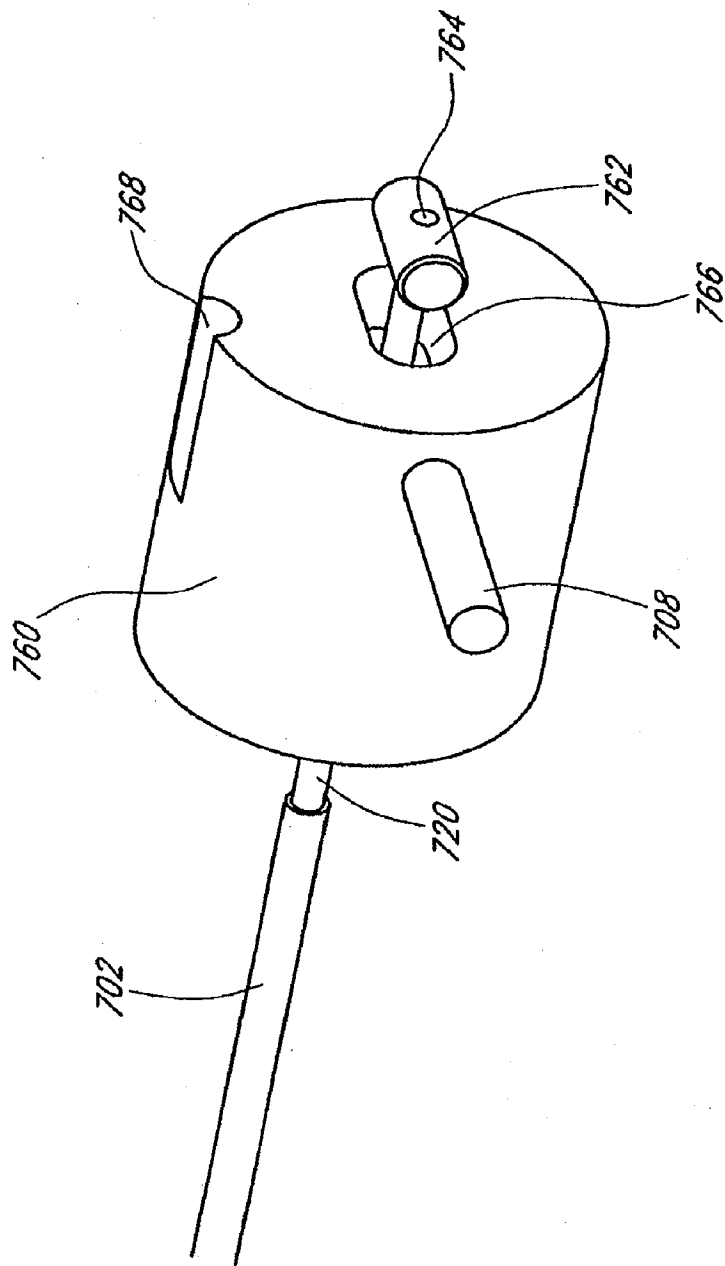


FIG. 15

U.S. Patent

Jan. 24, 2012

Sheet 22 of 24

US 8,100,942 B1

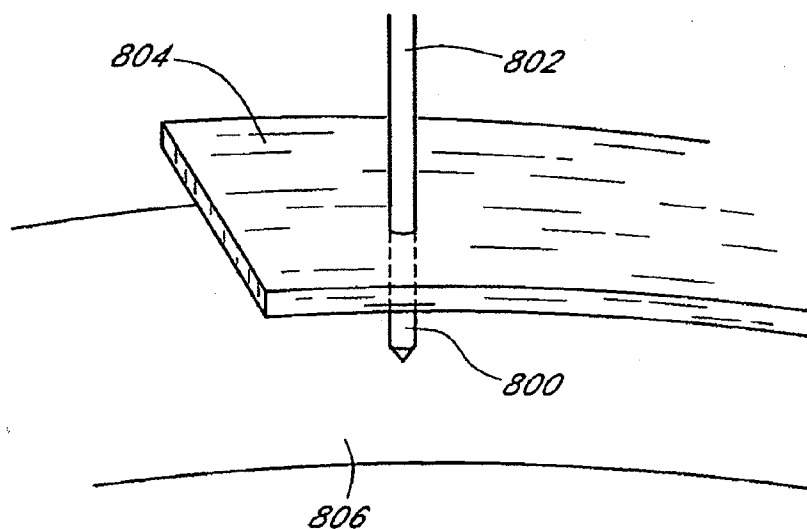


FIG. 16A

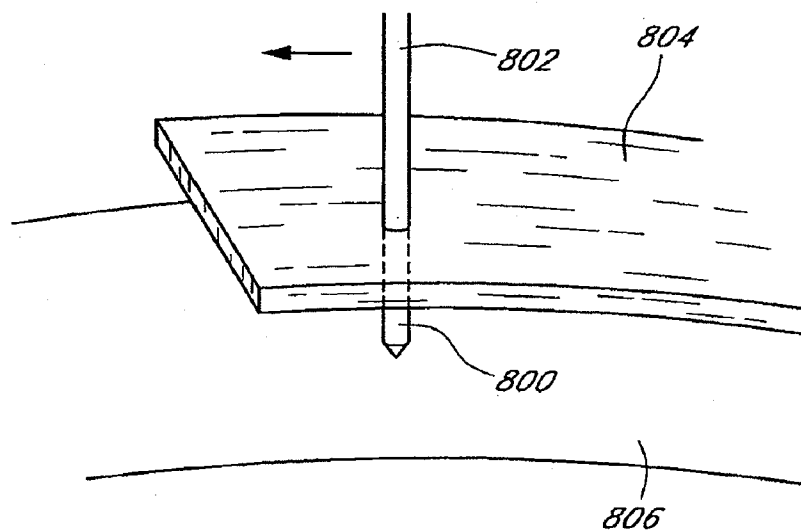


FIG. 16B

U.S. Patent

Jan. 24, 2012

Sheet 23 of 24

US 8,100,942 B1

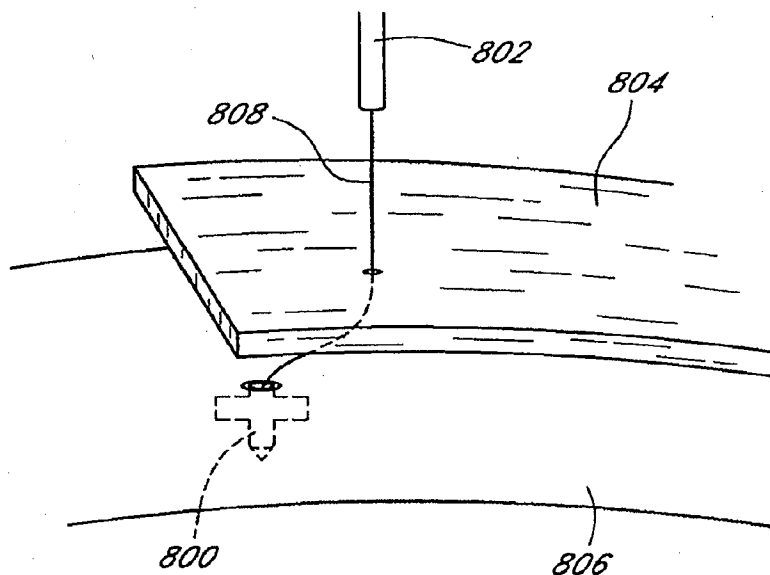


FIG. 16C

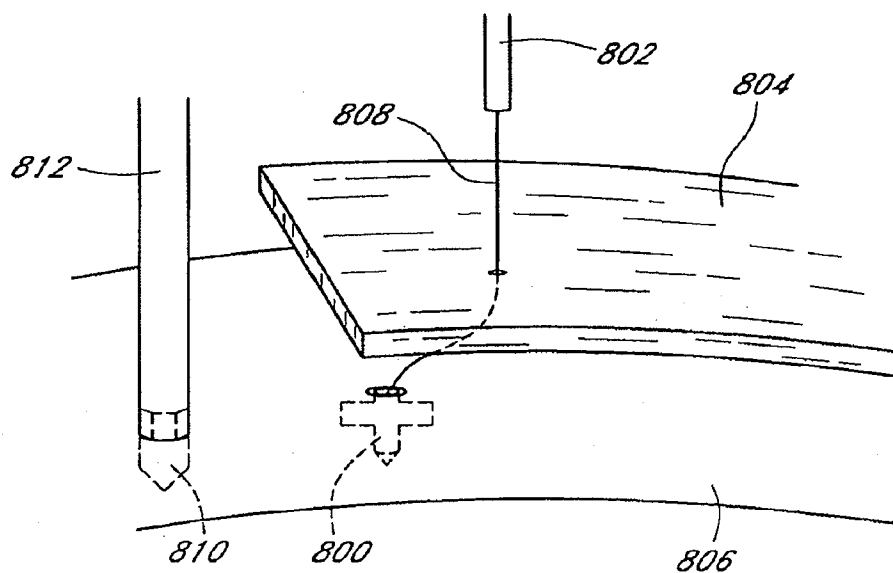


FIG. 16D

U.S. Patent

Jan. 24, 2012

Sheet 24 of 24

US 8,100,942 B1

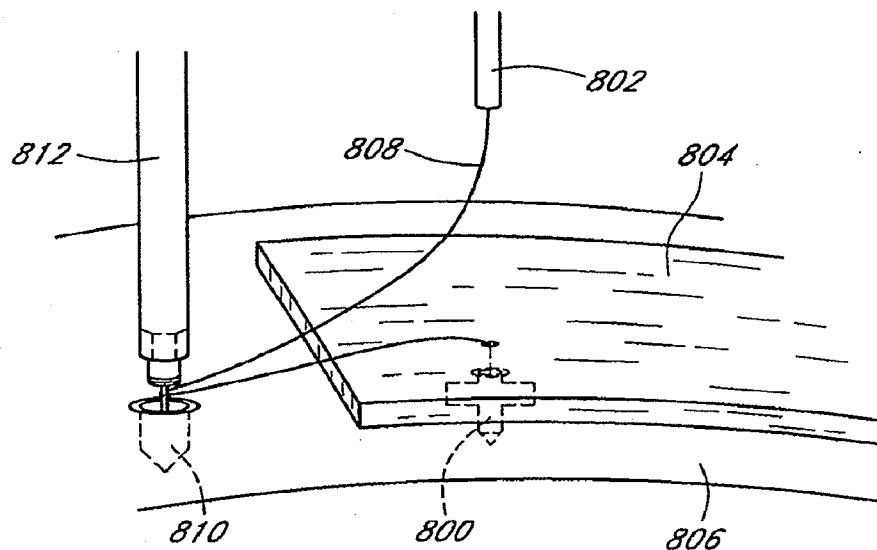


FIG. 16E

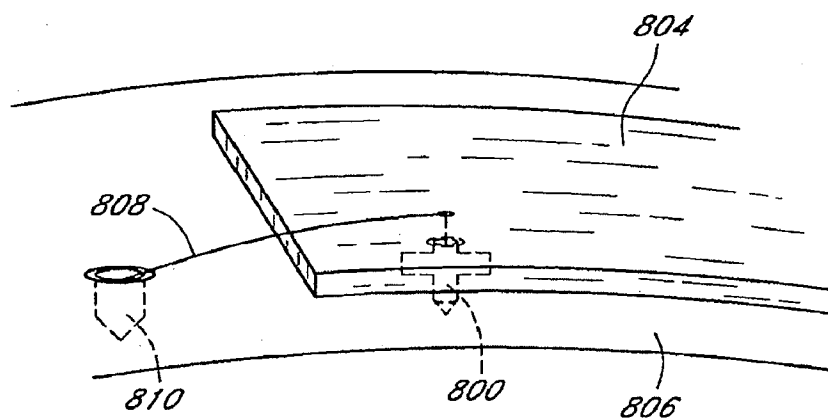


FIG. 16F

US 8,100,942 B1

1

## SYSTEM AND METHOD FOR ATTACHING SOFT TISSUE TO BONE

### RELATED APPLICATIONS

This application is a continuation of U.S. application Ser. No. 12/549,105, filed Aug. 27, 2009, which is a divisional of U.S. application Ser. No. 11/143,007, now U.S. Pat. No. 7,585,311, filed Jun. 1, 2005, which claims priority to U.S. Provisional Application Nos. 60/576,477, filed on Jun. 2, 2004; 60/610,924, filed on Sep. 17, 2004; and 60/634,174, filed on Dec. 7, 2004; all of which are incorporated herein by reference in their entirety.

### BACKGROUND OF THE INVENTION

#### 1. Field of the Invention

The present invention relates to medical devices and procedures. More particularly, the present invention relates to devices and methods for securing soft tissue to a rigid material such as bone.

#### 2. Description of the Related Art

There are several medical procedures where a surgeon needs to attach soft tissue such as tendons or other soft connective tissue to bone. One common example is a torn rotator cuff, where the supraspinatus tendon has separated from the humerus causing pain and loss of ability to elevate and externally rotate the arm. To repair a torn rotator cuff, typically a surgical procedure is used to suture the torn tendon to the bone using a variety of methods. Some procedures utilize large incisions and involve complete detachment of the deltoid muscle from the acromion. Small diameter holes are made in the bone for passing suture material through the bone to secure the tendon. Such large incision procedures are traumatic, causing prolonged pain and recovery time. Other procedures make small incisions and use arthroscopic techniques to attach sutures using either small diameter holes or a bone anchor. However, it is difficult to manipulate sutures within the surgical site using arthroscopic techniques. In addition, when knot tying is used to secure the suture to a bone anchor, it is difficult to properly adjust the tension of the suture while tightening the knot. Similarly, when the suture is attached to a bone anchor prior to insertion of the anchor into the bone, it is difficult to judge the appropriate point of attachment so that the suture will be properly tensioned upon insertion of the bone anchor into the bone. Thus, there is a need for methods and devices that allow easy arthroscopic attachment of a suture to a bone anchor after the anchor is inserted into the bone without the use of knot tying.

### SUMMARY OF THE INVENTION

The present invention is particularly suited for use in arthroscopic procedures, including but not limited to rotator cuff surgery. More broadly, it can be used in any procedure in which it is desired to fix a suture to a solid object without tying of knots, including not only arthroscopic procedures, but also open surgery, and can be used for such diverse purposes as bladder neck suspension, tendon and ligament affixation or repair, prosthetic attachment, and rotator cuff repair.

In one embodiment, the invention includes an anchor for securing a suture to bone, including an anchor base adapted to be securely fixed into the bone and a suture securing mechanism coupled to the anchor base and positioned proximally relative to the anchor base, the mechanism adapted to receive and secure a suture moved laterally into the

2

In another embodiment, the invention includes an anchor for securing a suture to bone, including an anchor base adapted to be securely fixed into the bone, a first surface coupled to the anchor base and positioned proximally relative to the anchor base, and a second surface coupled to the anchor base and positioned proximally relative to the anchor base, wherein the first and second surfaces are adapted to be relatively positioned in at least two configurations, one of the configurations such that a gap is present between the first and second surfaces so that the suture can be positioned between the first and second surfaces by moving the suture laterally into the gap, and the other of the configurations such that the first and second surfaces are in close proximity so that the suture can be securely clamped between the first and second surfaces.

In another embodiment, the invention includes a method of attaching soft tissue to bone, including passing a length of suture over the soft tissue, inserting an anchor into the bone, and securing the length of suture to the anchor after the inserting without passing an end of the length of suture through any aperture in the anchor and without tying any knots.

In another embodiment, the invention includes a method of attaching soft tissue to bone, including inserting a first anchor through the soft tissue, wherein the first anchor comprises a length of suture fixedly secured to the first anchor prior to insertion, inserting the first anchor into the bone, passing the length of suture over the soft tissue, and fixedly securing, after the passing, the length of suture to a second anchor.

In another embodiment, the invention includes a method of attaching soft tissue to bone, the soft tissue comprising a first surface adjacent to the bone's surface and a second surface opposite the first surface, the method including inserting a first portion of a length of suture into the second surface of the soft tissue, passing a second portion of the length of suture over the second surface of the soft tissue, inserting a first anchor with no suture coupled thereto into the bone, and fixedly securing the length of suture to the inserted first anchor, with the proviso that no part of the first portion of the length of suture is passed out of the second surface of the soft tissue.

In another embodiment, the invention includes a method of attaching soft tissue to bone, including inserting a first anchor with a length of suture pre-coupled thereto through the soft tissue, inserting the first anchor into the bone, inserting a second anchor with no suture coupled thereto into bone, passing the length of suture over the soft tissue, and fixedly securing the length of suture to the inserted second anchor.

In another embodiment, the invention includes a method of attaching soft tissue to bone, the method including inserting a first, second, and third anchor into the bone, fixedly securing a first length of suture over the soft tissue to the first and second anchors, and fixedly securing a second length of suture over the soft tissue to the first and third anchors.

In another embodiment, the invention includes an anchor for securing a suture to bone, the anchor including an anchor base adapted to be securely fixed into the bone, the anchor base comprising a first proximal surface and an anchor top, the anchor top comprising a distal member coupled to the anchor base and a first proximal member comprising a first distal surface, wherein the anchor top is adapted to couple to the anchor base in at least two configurations, one of the configurations such that the first distal surface is above the bone's surface when the anchor base is securely fixed into the bone, such that a suture can be freely passed between the first proximal and first distal surfaces above the bone's surface, and the other of the configurations such that the first distal

US 8,100,942 B1

3

surface is in close proximity to the first proximal surface, such that a suture can be securely clamped between the first proximal and first distal surfaces.

In another embodiment, the invention includes an anchor for securing a suture to bone, the anchor including a substantially hollow cylinder comprising an open end and comprising a portion of its walls cut in such a manner so as to allow the cylinder to deform under stress and form lateral protrusions, a substantially pointed tip coupled to the cylinder opposite the open end, wherein the pointed tip is adapted to pierce the bone, and a suture receiver coupled to the pointed tip and positioned within the substantially hollow cylinder so that a suture may be attached to the suture receiver and extend through the cylinder and out of the open end.

#### BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 depicts attaching soft tissue to bone using a single bone anchor and a stitch.

FIG. 2 depicts attaching soft tissue to bone using a two bone anchors with a suture stretched there between.

FIGS. 3A-3C depict various geometries of bone anchors and suture patterns for attaching soft tissue to bone.

FIGS. 4A-4D depicts the base of a two-part suture anchor that can be inserted into bone.

FIGS. 5A-5C depicts the top of a two-part suture anchor.

FIGS. 6A and 6B depict the suture anchor top of FIGS. 5A-5C inserted into the suture anchor bottom of FIGS. 4A-4D.

FIGS. 7A and 7B depict a suture anchor inserter.

FIG. 8 depicts components on a suture anchor inserter for attaching to bone and manipulating a suture anchor.

FIGS. 9A-9E depicts manipulation of a suture anchor using a suture anchor inserter to insert the suture anchor into bone and attach suture material to the suture anchor.

FIGS. 10A and 10B depict a piercing bone anchor in an un-deployed (FIG. 10A) and deployed (FIG. 10B) state.

FIG. 11 depicts a piercing bone anchor tip.

FIG. 12 depicts an anchor inserter for inserting a piercing bone anchor.

FIG. 13 depicts the interface between a piercing bone anchor and an anchor inserter.

FIG. 14 is a cut-away view of a bone anchor inserter.

FIG. 15 depicts a safety switch mechanism for a bone anchor inserter.

FIGS. 16A-16F depict a method for attaching soft-tissue to bone using a piercing bone anchor and a suture capturing anchor.

#### DETAILED DESCRIPTION OF THE CERTAIN EMBODIMENTS

In various embodiments, soft tissue may be attached to bone utilizing one or more bone anchors with suture attached thereto. As used herein, "suture" refers to any flexible structure that can be stretched between two or more anchors and includes, without limitation, traditional suture material, single or multiple stranded threads, or a mesh structure. In some embodiments, suture is passed over the top of the soft tissue so that the suture can press the soft tissue against the bone. In one embodiment, a length of suture is attached to a single bone anchor. One non-limiting example, depicted in FIG. 1, includes stitching the suture 10 to the soft tissue 12, such as by an incline mattress stitch, and then securing the suture 10 to the single bone anchor 14 that is inserted into the bone 16. However, in other embodiments, a length of suture is attached to multiple bone anchors. The use of multiple bone

4

anchors increases the footprint over which the suture material presses the soft tissue against bone. One non-limiting example, depicted in FIG. 2, includes two bone anchors. One anchor 20 is positioned in a medial location underneath the soft tissue 12 and a second anchor 22 is positioned lateral to the soft tissue 12. The suture 10 is attached to both anchors.

In one embodiment, the suture 10 is attached to the lateral bone anchor 22 only after the medial bone anchor 20 is inserted and the suture 10 is passed over the soft tissue 12. In one embodiment, the suture 10 is attached to the medial bone anchor 20 prior to insertion of the medial bone anchor 20. Thus, in this embodiment, the surgeon does not need to pass the suture through the soft tissue 12 from beneath the soft tissue 12. In one embodiment, the procedure involves inserting the medial bone anchor 20 with suture 10 pre-attached through the soft tissue 12. The medial bone anchor 20 may then be moved laterally relative to the bone 16 in order to pull the soft tissue 12 laterally relative to the bone 16. After appropriate positioning of the soft tissue 12, the medial bone anchor 20 may then be inserted into the bone 16. The lateral bone anchor 22 may then be inserted into the bone 16. The suture 12 may then be passed over the soft tissue 12 and attached to the lateral bone anchor 22. In some embodiments, a lateral bone anchor 22 is provided to which suture 12 can be attached without tying any knots or without passing the suture 12 through any aperture in the lateral bone anchor 22.

In some embodiments, multiple anchors and multiple suture lengths may be used to provide a wider area of pressure of the soft tissue against bone. For example, as depicted in FIG. 3A, three anchors are used with two lengths of suture 26 and 28. Alternatively, a mesh structure 29 may be stretched between the three anchors. In another example, as depicted in FIG. 3B, four anchors are used with two lengths of suture. In still another example, as depicted in FIG. 3C, four anchors are used with four lengths of suture. In some embodiments, the individual suture lengths may be part of a larger continuous suture. For example, in FIG. 3A, the suture lengths 26 and 28 may be part of a larger length of suture such that the lengths 26 and 28 are joined at medial bone anchor 20. Those of skill in the art will appreciate that there are any number of anchor and suture geometries that can be used.

In some embodiments, the medial bone anchors 20 are designed so that they can be easily pierced through the soft tissue 12 and bone 16. In some embodiments, the lateral bone anchors 22 are designed so that they can easily capture suture material after insertion of the bone anchors 22. Together, these design features provide a suturing system and method that provides an increased footprint of suture pressure against the soft tissue 12 and ease of implementation for a surgeon.

For example, in some embodiments, the entire procedure may be done arthroscopically, with the surgeon needing only to insert the medial bone anchor 20 with suture optionally pre-attached through a first port, insert the lateral anchor 22 through a second port, pass the suture over the soft tissue 12 by capturing it from within the second port, and securing the suture to the lateral anchor 22. Accordingly, described below are certain embodiments of anchors adapted to capture suture material and anchors adapted to easily pierce through soft tissue and bone.

#### Suture Capturing Anchor

One embodiment is a bone anchor that allows easy capturing and securing of a suture after the bone anchor is inserted into the bone. In one embodiment, the bone anchor includes a suture securing mechanism positioned on the proximal end of the bone anchor (i.e., the end nearest the surface of the bone and the surgeon). In one embodiment, the suture securing mechanism allows a suture to be moved laterally into the



US 8,100,942 B1

5

mechanism. By "laterally," it is meant that the suture can be moved into the mechanism by moving the suture in a direction that is generally perpendicular to the axis of the suture. In other words, the suture can be moved into the mechanism without threading an end of the suture into the mechanism. In one embodiment, the suture can be fixedly secured within the mechanism without tying any knots. By "fixedly secured," it is meant that the suture within the securing mechanism cannot be easily moved relative to the bone anchor.

One embodiment is a bone anchor that allows easy attachment of suture material by clamping the suture material between two surfaces on the bone anchor. The bone anchor may be configured such that the bone anchor is inserted into the bone without the suture material attached. The two surfaces of the suture securing mechanism may be spaced apart so as to form a gap between the surfaces. The suture material may be passed between the two surfaces and tensioned as desired followed by clamping of the two surfaces together, thereby clamping the suture material there between.

In one embodiment, the bone anchor consists of two parts: an anchor base and an anchor top. The anchor base may be designed to be inserted into a hole in the bone with a proximal surface facing up. The anchor top may be coupled to the anchor base via a distal member. A proximal member on the anchor top may have a distal surface facing down toward the proximal surface on the anchor base. The coupling of the anchor top to the anchor base may be such that the anchor top can move relative to the anchor base such that it can be positioned in one configuration where there is space between the proximal surface on the anchor base and the distal surface on the proximal member of the anchor top. In another configuration, the proximal member of the anchor top may be positioned such that there is very little space, if any, between the proximal surface on the anchor base and the distal surface on the proximal member of the anchor top. Thus, in the first configuration, suture material may be easily passed between the two surfaces and tensioned as desired. In the second configuration, the suture material may be clamped between the two surfaces such that the suture is secured to the bone anchor.

One embodiment of an anchor base 100 is depicted in FIGS. 4A through 4D. FIG. 4A is a perspective view showing the side 101 and bottom 102 of the anchor base 100. The bottom 102 of the anchor base 100 may advantageously be tapered to facilitate insertion of the anchor base 100 into bone. In some embodiments, a hole is predrilled into the bone to facilitate insertion of the anchor base 100. In other embodiments, the anchor base 100 is forced directly into the bone, thereby creating the hole. The sides 101 of the anchor base 100 comprise threads 104 so that the anchor base 100 may be inserted into bone using a screwing action. In some embodiments, the anchor base 100 may be tapped to start the threads 104 into the bone followed by screwing the anchor base 100 into the bone. When the hole in the bone is pre-drilled, the hole is advantageously drilled with a diameter smaller than the diameter of threads 104 so that the threads engage the bone through the sides of the hole. It will be appreciated that means other than threads may be used to secure the anchor base 100 to bone. For example, angled protrusions may be used that provide greater resistance to removal of the anchor base 100 than to insertion. The protrusions may be static or deployable once the anchor is inserted.

The top of anchor base 100 preferably includes a structure 106 for facilitating the driving or screwing of the base 100 into the bone. In the illustrated embodiment, this comprises a hex nut structure 106 that facilitates engagement with a hex nut driver for screwing the anchor base 100 into the bone. It

6

will be appreciated that other structures known in the art for engaging tools used for screwing action may be used instead of hex nut structure 106, and that this structure can be indented into or extending out from the top of the anchor base 100, or can alternatively be formed on the sides of the anchor base 100.

With reference to FIG. 4B, which is a perspective view of the top and side of anchor base 100, the top (proximal end) comprises a hole 108 in the center for receiving the anchor top, which is described below. The top of anchor base 100 also contains a suture gripping structure such as a circular groove 110 that may be concentric with hole 108. Because of groove 110, the proximal surface of anchor base 100 is not flat and comprises top surfaces 112 and 114, bottom surface 116, and side surfaces 118 and 120. In some embodiments, some or all of these surfaces may be textured such as with a scallop shape or grooves so as to inhibit movement of suture material pressed against the surfaces. Although a grooved surface is illustrated, it will be appreciated that other shapes for the proximal surface of anchor base 100 are also contemplated, including multiple concentric grooves, a series of protruding ridges, a "vee" shaped channel, or any other suitable structure that permits a suture to be securely locked against the top or proximal end of the anchor base 100.

Hole 108 in anchor base 100 is an opening into a central ("axial") bore into the anchor base 100. The sides of the central bore preferably include structures for gripping something inserted into the central bore, such as ratchet structures 122. FIG. 4C show a central ratchet bushing 126 that fits within the central bore and contains the ratchet structures 122. In the embodiment of FIG. 4C, the ratchet structures 122 are constructed by cutting U shaped cuts into bushing 126. The U shaped cuts then define tabs that make up the ratchet structures 122. It will be appreciated that other shapes and methods for making ratchet structures may be used. The purpose of ratchet bushing 126 is to receive the anchor top and secure it to the anchor base 100. It will be appreciated that other methods of securing the anchor top to the anchor base 100 may be used, such as a frictional fit or threading. Furthermore, the anchor top may be coupled to the anchor base 100 using means other than hole 108 and bushing 126. For example, the anchor top may be coupled via structures at the perimeter rather than the center or by a hinge.

FIG. 4D depicts a cross section through the center of anchor base 100. This view illustrates central bore 130 and groove 110. The proximal surfaces 112, 114, 116, 118, and 120 are also apparent. Central bore 130 preferably does not extend all the way through the anchor base 100. Instead, a smaller bore 132 is present at the distal end 102 of the anchor base 100. Smaller bore 132 is used to receive a wire connected to an anchor inserter. It will be appreciated that other structures than bore 132 may be used for attaching the wire and that other means than a wire may be used to secure the anchor to the anchor inserter.

FIGS. 5A through 5C illustrate one embodiment of an anchor top 200. FIG. 5A provides a perspective view of the side and top of the anchor top 200 and FIG. 5B provides a perspective view of the side and bottom of the anchor top 200. Anchor top 200 has two members, a distal member 202 and a proximal member 204. The distal member 202 comprises an elongated shaft, the longitudinal direction of which shall be considered to run along the axis of the distal member 202. A series of grooves or other mating or locking surfaces or structures 206 exist along a portion of the outside surface of the shaft. The distal member 202 is designed to be inserted into the central bore 130 of the anchor base 100. The ratchet structures 122 in the anchor base 100 engage grooves 206 to

US 8,100,942 B1

7

couple the anchor top 200 to the anchor base 100. The ratchet structures 122 are oriented such that the distal member 202 can be easily moved in the distal direction in central bore 130 with the ratchet structures 122 snapping into the grooves 206 as the distal member 202 is moved downward. However, when the ratchet structures 122 are snapped into grooves 206, proximal movement of distal member 202 is inhibited. Thus, the anchor top 200 may be ratcheted down into anchor base 100. Because the ratchet structures 122 exist along substantially the entire surface of the central bore 130 (see FIG. 4C), the anchor top 200 may be coupled to the anchor base 100 in several positions. In other words, in one embodiment the anchor top 200 need not be ratcheted into the anchor base 100 as far as it will go for it to be secured to the anchor base 100.

The proximal member 204 of anchor top 200 is generally cylindrical in shape with a diameter larger than distal member 202. A hole 208 may advantageously be provided in the center of proximal member 204. With reference to FIG. 5B, the bottom of distal member 202 also contains a hole 210. Holes 208 and 210 open into a central bore through the anchor top 200. This central bore allows the wire referred to above to extend through the anchor top 200 to be secured to bore 132 in the anchor bottom 100, thus allowing the anchor bottom 100 to be attached to an anchor inserter while still allowing anchor top 200 to be ratchet into anchor bottom 100. FIG. 5B also illustrates that proximal member 204 contains a groove 212 in its distal surface. Thus, the distal surface of proximal member 204 is not flat and comprises distally facing surfaces 214 and 216 and side facing surfaces 218 and 220. In some embodiments, some or all of these surfaces may be textured such as with a scallop shape or grooves so as to inhibit movement of suture material pressed against the surfaces. In some embodiments, texturing in the distal surfaces of proximal member 204 match texturing in the proximal surfaces of anchor base 100. It will be appreciated that the illustrated embodiments represent only one possibility; thus, other shapes for the distal surface of proximal member 204 may also be used. FIG. 5C depicts a cross section through the center of anchor top 200. In this figure, the central bore 226 is depicted as are surfaces 214, 216, 218, and 220 and grooves 206.

FIGS. 6A and 6B depict cross sections showing how the anchor top 200 may be coupled to anchor base 100 to form the complete anchor 300. In FIG. 6A, the anchor top 200 is coupled to anchor base 100 with the proximal member 204 separated from the anchor base 100. The anchor top 200 is secured to anchor base 100 by distal member 202 extending into central bore 130 of the anchor base 100. The distal member 202 is secured by ratchet structures (not shown) engaging grooves 206 in distal member 202. Central bore 226 in anchor top 200 and central bore 130 in anchor base 100 allow a wire to extend into the top of the anchor 300 and be secured to bore 132. Alternatively, the wire may be secured at other locations within central bore 130. Thus the wire, which can be coupled to an anchor inserter, can hold the entire anchor assembly 300 and still allow anchor top 200 to move relative to anchor base 100 and the wire.

FIG. 6B depicts the anchor assembly 300 with the distal member 202 of anchor top 200 ratcheted all the way into central bore 130 in anchor base 100. In this configuration, it can be seen that proximal surfaces 112, 114, 116, 118, and 120 of the anchor base 100 and distal surfaces 214, 216, 218, and 220 of the proximal member 204 of anchor top 200 form passageways 302 and 304. The size of passageways 302 and 304 are advantageously such that when a suture passes through them, it will be compressed so that it is securely attached to the anchor 300.

8

Another embodiment of the present invention is an inserter designed to insert and manipulate an anchor such as described in FIGS. 1-3. One such inserter 400 is depicted in FIGS. 7A and 7B. Inserter 400 comprises a handle 402 and an outer tube 404. As depicted in FIG. 7A, the handle 402 comprises a cover 403. FIG. 7B depicts the inserter 400 with cover 403 removed. Not depicted in FIGS. 7A and 7B are an inner tube disposed inside outer tube 404 and a wire disposed within the inner tube. As will be described in more detail below, the inner and outer tubes may be used to manipulate an anchor 300 such as that described in FIGS. 4-6. The wire may be used to couple the inserter 400 to the anchor 300 as described above. Inserter 400 also comprises an outer tube manipulator 406 and a wire manipulator 408. Outer tube manipulator 406 comprises release button 410. Outer tube manipulator 406 is securely attached to outer tube 404. Outer tube manipulator 406 may move longitudinally relative to handle 402 and the inner tube when release button 410 is pressed. Thus, when outer tube manipulator 406 is moved, outer tube 404 also moves.

Wire manipulator 408 comprises wire grabber 410 to which the wire is attached. The wire extends from wire grabber 410, through handle 402, and then through the inner tube. In one embodiment, wire manipulator 408 also comprises a release button 412. When release button 412 is pressed, the wire manipulator 408 may be pressed into the handle 402 to contact and thus provide additional tension on the wire. When in use, the additional tension causes the anchor base 100 to move relative to inserter 400. When enough tension is provided to the wire by wire manipulator 408, the wire may break free from the anchor 300 at its attachment point in bore 132 or at some other predetermined location along the wire. It will be appreciated that any suitable breakable attachment means may be used for securing the wire to the anchor 300. For example, the wire may be frictionally secured into bore 132 or it may be welded to the anchor base 100 using a weld that is weaker than the wire itself or a portion of the wire where breaking is desired may be weakened. In one embodiment, the wire is notched so as to create a weaker region in the wire that will break upon application of suitable force.

The tip 414 of outer tube 404 is depicted in more detail along with inner tube 420, wire 422, and anchor 300 in FIG. 8. The end of outer tube 404 may comprise a hex nut driver structure 424 for receiving the hex nut structure 106 of anchor base 100. Of course, any other suitable engagement structure can be provided on the inserter 400 and the anchor base 100 in order to facilitate placement of the anchor base 100. Wire 422 extends out of inner tube 420 and into the central bore in the anchor top 200 to attach to anchor base 100 as described above. In some advantageous embodiments, the wire length and tension is adjusted such that the proximal member 204 of anchor top 200 butts against the end 426 of inner tube 420.

FIGS. 9A through 9E depict how inserter 400 and anchor 300 may be used to insert the anchor 300 into bone and attach a suture to it. FIG. 9A depicts the configuration for inserting the anchor 300 into bone. Outer tube 404 and outer tube manipulator 406 (see FIGS. 7A and 7B) are positioned relative to inner tube 420 and handle 402 (see FIGS. 7 and 8) so that the outer tube 404 engages hex nut structure 106 in the anchor base 100. It is advantageous in this configuration for the anchor top 200 to be in a position relative to the anchor base 100 such as depicted in FIG. 6A. In the configuration of FIG. 9A, a surgeon may then screw the anchor base 100 into bone by twisting handle 402 of inserter 400 (see FIGS. 7A and 7B).

After the anchor base 100 is inserted into the bone, the outer tube 404 may be slid backward relative to the inner tube 420 and handle 402 to expose the anchor top 200 such as in

US 8,100,942 B1

9

FIG. 9B. One or more lengths of suture 600 may then be placed in the space between the distal surface 602 of the proximal member 204 of anchor top 200 and the proximal surface 604 of the anchor base 100 by moving the suture laterally into the space as depicted in FIG. 9C. The suture 600 may be manually tensioned as desired. In some embodiments, tensioning of the suture 600 is aided by pulling the suture 600 against the distal member 202 of the anchor top 200.

After appropriate tensioning of suture 600, wire manipulator 408 may be pressed to tension the wire, causing the handle 402 of the inserter 400 and the inner tube 420 to be pulled down towards the anchor base 100 so that inner tube 420 ratchets the anchor top 200 down into the anchor bottom 100 as depicted in FIG. 9D. As the anchor top 200 is pushed axially down, suture 600 will be clamped between the distal surface 602 of the proximal member 204 of anchor top 200 and the proximal surface 604 of the anchor base 100 (see also FIG. 9C). The clamping will force the suture to be compressed within the passageways 302 and 304 depicted in FIG. 6B and thus be secured to anchor 300. The fit between the anchor top 200 and the anchor base 100 in the clamping region is such that the suture 600 is firmly gripped, but is not cut, when it is clamped in place. Appropriate edges that may contact the suture are preferably beveled or rounded to avoid damage to the suture. After anchor top 200 is ratcheted sufficiently into anchor base 100, wire manipulator 408 (see FIGS. 7A and 7B) in inserter 400 may be compressed further to further tension wire 422 (see FIG. 8) such that wire 422 breaks free from its attachment to anchor base 100, thus leaving the anchor 300 free from inserter 400 with suture 600 securely attached as depicted in FIG. 9E.

Although a particular inserter device for inserting and manipulating anchor 300 has been described, it should be understood that other inserter designs may be used for manipulating the parts of anchor 300 described above to insert the anchor into bone and secure suture material to the anchor. For example, it may be possible to use separate tools for inserting the anchor and securing the suture material. In addition, in alternative embodiments, the anchor base 100 may be connected to the anchor top 200 throughout the procedure, or the anchor base may be separately inserted into the bone, and the anchor top can be attached thereafter by axially sliding the distal end of the anchor top 200 into the hole 108 in the anchor base 100.

It will be appreciated by those of skill in the art that the anchor 300 and inserter 400 provide a system for easy attachment of a suture to bone. The anchor 300 may be inserted into bone with minimal disruption of surrounding tissue. Only an access route having the diameter of the outer tube 404 and the anchor base 100 is required. Furthermore, the suture can be securely attached to the anchor 300 and tensioned as desired without having to insert additional instrumentation into the site or without performing any cumbersome attachment maneuvers such as knot tying. It should also be appreciated that the general principle illustrated by this system of inserting an anchor into bone without having suture material pre-attached and then attaching suture to the anchor without tying any knots may be implemented using any appropriate system other than the specific embodiments depicted in FIGS. 4-9. Tissue and Bone Piercing Anchor

One embodiment is a bone anchor adapted for piercing through the soft tissue and into underlying bone. In one embodiment, the suture material may be pre-attached to the piercing bone anchor so that after implantation, a suture passes from the bone anchor through to the top of the soft tissue for easy passing over the soft tissue. In one embodiment, the piercing bone anchor has two configurations, a first

10

configuration having a small diameter for easy piercing through soft tissue and bone and a second deployed configuration where structures such as protrusions are deployed to prevent the bone anchor from being easily removed from the bone.

In one embodiment, the anchor includes a substantially hollow cylinder having a portion of its walls cut in such a manner so as to allow the cylinder to deform under axial stress and form lateral protrusions. The lateral protrusions may thus prevent the anchor from being easily removed from the bone after deployment. In one embodiment, the anchor comprises a pointed tip coupled to the hollow cylinder for piercing the soft tissue and bone. In one embodiment, suture is pre-attached to the pointed tip inside of the hollow cylinder. In other embodiments, suture is pre-attached at other locations on the piercing anchor, such as at the proximal end of the hollow cylinder.

One embodiment of a deployable piercing anchor is depicted in FIGS. 10A and 10B. In FIG. 10A, the anchor is depicted in a pre-deployed state. The anchor includes a substantially hollow cylinder 650 with a plurality of cuts 652 in the side of the cylinder 650. The cylinder 650 is open on one end 654. On the other end, a pointed tip 656 is disposed, allowing the anchor to pierce through soft tissue and bone. In FIG. 10B, the anchor is depicted in a deployed state. Stress is applied in an axial direction such that the cylinder 650 collapses along cuts 652 so as to form two lateral wings 660. The lateral wings 660 prevent the anchor from being removed from the bone. Hinges 662 connect one end of each wing to either the top or the bottom parts of anchor body. These hinges deform and fold, in the plane tangent to the anchor body at that point when the anchor is deployed. A strip of material 664 connects the top and bottom wing on each side of the anchor body, and serves as a hinge between the two as well as aiding in alignment of the wings during deformation. The tips of the wings adjacent to the connecting strip 664 utilize rolling edges 666, which ensure uniform alignment and smooth transition during deformation. Those of skill in the art will appreciate that any number of geometries of cuts in the cylinder 650 may be utilized to create a deformable structure that will produce lateral protrusions upon exposure to stress.

In some embodiments, structures may be positioned within the cylinder 650 for attaching sutures and engaging with an anchor inserter. In one embodiment, such structures are coupled to the anchor tip 656 within the cylinder 650. FIG. 11 depicts one such embodiment. Attached to the tip 656 is a structure 670 through which there is an aperture 672. The structure 670 may be adapted to engage the inner surface of cylinder 650 for attaching the tip 656 to the cylinder 650. The attachment mechanism may be by forced fit, frictional fit, threads, welding, adhesive, or any other suitable means. Suture material may be threaded through the aperture 672 in order to attach the suture to the anchor. The suture material may be secured to the tip 656 by tying the suture around structure 670, tying a knot in the end of the suture that prevents it from being pulled through the aperture 672, clamping the suture between the structure 670 and the inside of the cylinder 650, adhering the suture to structure 670 by welding or adhesive, or any other suitable means. In one embodiment, the suture material is attached to the anchor at tip 656 prior to use of the anchor.

An anchor inserter attachment structure 674 may also be coupled to the tip 656. This structure 674 may couple to an anchor inserter through a wire or any other suitable means. The attachment between the anchor inserter and the anchor at this point may be used to apply axial stress to the anchor for



US 8,100,942 B1

11

deploying the anchor as described above. The attachment at this point may also serve to keep the anchor attached to the inserter prior to deployment.

One embodiment of an anchor inserter suitable for use with the above-described anchor is depicted in FIG. 12. The anchor inserter comprises a grasping handle 700 to which is attached an outer sleeve 702 which is fixed relative to the handle 700. The piercing anchor 704 is disposed at the end of the sleeve 702. A deployment lever 706 may be pressed by a user to deploy and detach the anchor 704 as described below. A safety switch 708 may be provided to prevent the anchor 704 from being deployed prematurely. A spool 710 may be provided at the proximal end of the handle 700 for holding excess suture. A lid 712 may be provided for gaining access to the inner components of the inserter.

FIG. 13 depicts the anchor 704 coupled to the inserter. As described above, the anchor 704 comprises a hollow cylinder 650 with cuts in the sides and a pointed tip 656. Furthermore, as depicted in FIG. 11, a suture receiving aperture 672 and an inserter attachment structure 674 are attached to the pointed tip 656 within the cylinder 650. The outer sleeve 702 of the inserter may fit over the open end 654 of the cylinder 650 or be flush with the open end 654. The outer sleeve 702 may thus hold the top part of the anchor 704 steady during insertion. In an alternative embodiment, the outer sleeve 702 may fit over the length of the cylinder 650 to prevent the cylinder 650 from deforming while it is being inserted into bone. In this alternative embodiment, the outer sleeve 702 may be retracted prior to deployment of the anchor. An inner tube 720 may be positioned within the outer sleeve 702 and the hollow cylinder 650 and contact the top surface of the anchor tip 656 (see FIG. 11). The inner tube 720 provides structural reinforcement of the anchor 704 and pushes against the tip of the anchor 704 while it is being driven into bone or tissue. The inner tube 720 may be fixed relative to the handle 712 and outer sleeve 702 during insertion, however, during deployment of the anchor 704, the inner tube 720 may be released by switching safety switch 708 so that the inner tube 720 can move axially relative to the outer sleeve 702 while the anchor cylinder 650 collapses. A wire may be positioned inside of the inner tube 720 running from within the handle 712 through the inner tube 720 to the anchor 704 and attached to the anchor inserter attachment structure 674. During deployment, the lever 704 may be pressed to pull the wire axially towards the handle 700. The axially movement of the wire forces the anchor 704 to press against outer sleeve 702 and stresses the cylinder 650, causing it to deform and deploy. During collapse of the cylinder 650, the inner tube 720 will also move in an axial direction toward the handle 700. Upon further stress on the wire, the wire may break free from the anchor inserter attachment structure 674, releasing the inserter from the anchor 704. Suture material may run from the inside of handle 700 through the inner tube 720 to attach to the anchor 704 through aperture 672 (see FIG. 11). Upon detachment of the anchor inserter from the anchor 704, the inserter may be withdrawn, leaving the inserted and deployed anchor with suture coming out of the open end 654 of the cylinder 650. The suture will still be coupled to the inserter through the inner tube 720, handle 700, and around spool 710. Those of skill in the art will appreciate other inserters and mechanisms that may be used to insert and deploy the piercing anchors described herein. For example, rather than axially stressing the anchor 704 by pulling the tip 656 in a proximal direction, the cylinder 650 may be pushed in a distal direction to deform the cylinder 650.

FIG. 14 is a cut-away view of the handle 700, showing the inner workings of the anchor inserter. The suture material attached to a piercing anchor at the tip of the inserter may pass

12

through the central bore of the inner tube 720 and through a bore 750 in the handle 700. The suture material may then pass through a hole 752 in the end of the handle 700 and be wrapped around the spool 710, which may be integral with the handle 700. The wire attached to the anchor inserter attachment structure 674 in the anchor may also pass through the central bore of the inner tube 720 and may then proceed around a pulley 754 and attach securely to the handle 700 at point 756. The pulley 754 may be attached to the lever 706. When the lever 706 is pressed down, the pulley 754 will move toward the back end of the handle 700, causing the wire attached to the anchor to retract. Because of the use of pulley 754, the wire will retract twice the distance as the pulley 754 moves.

The safety switch 708 may be used to prevent the lever 706 from being pressed and prevent the inner tube 720 from moving unless the safety switch 708 is in the correct position. The safety mechanism operates via a drum 760 disposed within the handle 700 to which the safety switch 708 is attached. Moving the safety switch 708 rotates the drum 760 within the handle 700. FIG. 15 shows the drum 760 and safety switch 708 mechanism in more detail. The inner tube 720 passes through a central bore in the drum 760. On the other side of the drum 760, the inner tube 720 is attached to a stopper 762. The stopper 762 has a through-hole 764 to permit passage of the deployment wire and suture. The stopper 762 may be positioned within a cavity 766 in the end of the drum 760. A second similarly shaped cavity may be disposed within the handle 700. The stopper 762 and attached inner tube 720 may only be allowed to move axially relative to the handle 700 when the safety switch 708 and drum 760 is rotated so that the cavity 766 in the drum 760 is aligned with the matching cavity in the handle 700. When the cavities are aligned, the stopper 762 is allowed to move from the cavity 766 to the cavity in the handle 700, thus allowing the inner tube 720 to move axially and the anchor to be deployed.

Additionally, the drum 760 comprises a groove 768. A spring-loaded sliding pin 770 (see FIG. 14) may be coupled to the lever 706. The lever 706 can only be moved when the drum 760 and switch 708 are rotated so that groove 768 is aligned with the pin 770. Thus, both the stopper 764 and the pin 770 prevent the anchor from being deployed unless the switch 708 is in the correct position.

Those of skill in the art will appreciate other mechanisms that could be used for deploying a deployable anchor and providing safety mechanisms to prevent premature deployment.

Example Using a Piercing Anchor and a Suture Capturing Anchor

The above-described anchors may be used in a surgical procedure for attaching soft tissue to bone. One example of such a procedure is depicted in FIGS. 16A through 16F. In FIG. 16A, the piercing anchor 800 attached to an anchor inserter 802 as described above is pierced through soft tissue 804 that has become detached from underlying bone 806. In FIG. 16B, the anchor inserter 802 is moved laterally relative to the bone 806 so as to stretch the soft tissue 804 laterally relative to the bone 806. Once the soft tissue 804 has been stretched to the desired position, the anchor 800 is inserted into the bone 806 and the anchor 800 is deployed as described above and the inserter 802 is detached from the anchor 800, leaving a suture 808 attached to the anchor 800 and extending through the soft tissue 804. The anchor 800 may be inserted into bone 806 by tapping on the inserter 802 with a hammer or by any other suitable means of applying axial force. FIG. 16C depicts the deployed anchor 800 with attached suture 808. The suture 808 will extend into the inserter 802.

US 8,100,942 B1

13

Next, as depicted in FIG. 16D, a suture capturing anchor 810 is inserted into the bone 806 using the inserter 812 as described above. In FIG. 16E, the inserter 812 is then retracted to expose the suture capturing mechanism. The suture 808 is then passed over the soft tissue 804 and laterally moved into the suture capturing mechanism and tensioned. Finally, as depicted in FIG. 16F, the suture capturing mechanism is deployed to capture the suture 808, the anchor inserter 812 is detached from the anchor 810, and the suture 808 is cut to detach it from the suture inserter 802. The result is a length of suture 808 between the bone anchors 808 and 810 that presses the soft tissue 804 against the bone 806. Multiple anchors and sutures may be used to produce geometries such as depicted in FIGS. 2 and 3 and variations thereof.

It will be appreciated that there are numerous stitches, suture threading patterns, and anchor patterns that may be used to secure soft tissue to bone by the methods and devices described herein. These variations as well as variations in the design of the above described anchor devices and inserter devices are within the scope of the present disclosure.

#### Methods of Attaching Soft Tissue to Bone

Various embodiments include methods for attaching soft tissue to bone. In some embodiments, the methods include using the bone anchors described above. In one embodiment, a bone anchor is inserted into the bone and then a length of suture is passed over the soft tissue and secured to the anchor after inserting the anchor without tying any knots or without passing the suture through an aperture in the anchor. In some embodiments, the suture is secured to the anchor by laterally moving it into a securing mechanism. In one embodiment, securing the suture to the anchor includes clamping the suture between at least two surfaces on the anchor. In one embodiment, the anchor is not inserted further into the bone after securing the suture to it.

In another embodiment, a first anchor with a suture pre-attached is inserted through the soft tissue and into the bone. The suture may then be passed over the soft tissue and fixedly secured to a second bone anchor. In one embodiment, the first anchor is inserted by directly piercing the soft tissue and the bone. In one embodiment, lateral protrusion may be deployed on the first anchor to prevent the first anchor from being removed. In one embodiment, the suture may be coupled to the second bone anchor prior to insertion and then fixedly secured after insertion. In this context, "coupled" means that the suture is attached to the bone anchor but not fixedly secured, such that the suture can move to some extent relative to the bone anchor. In an alternative embodiment, the suture is not coupled to the second bone anchor during its insertion.

In another embodiment, a first portion of suture is inserted into the proximal surface of the soft tissue. A second portion of the suture (e.g., the portion proximal to the inserted portion) is then passed over the proximal surface of the soft tissue and fixedly secured to a bone anchor. In one embodiment, the procedure may be performed without passing the first portion of the suture back out of the proximal surface of the soft tissue. In one embodiment, this result is accomplished by the first portion of the suture being attached to an anchor that is inserted through the soft tissue and into bone.

One embodiment includes inserting a first anchor with a pre-coupled suture through soft tissue and into bone. The suture may then be passed over the soft tissue and fixedly secured to a second anchor. In one embodiment, the pre-coupled suture is fixedly secured to the first anchor prior to insertion. In an alternative embodiment, the pre-coupled suture can move relative to the first anchor prior to insertion and is fixedly secured after insertion.

14

In another embodiment, multiple lengths of suture are attached to multiple anchors. In one embodiment at least three anchors are inserted into bone. A first length of suture may be secured between a first and second anchor and a second length of suture may be secured between the first and a third anchor. In one embodiment, the first anchor is positioned beneath the soft tissue and the second and third anchors are positioned laterally to the soft tissue. In an alternative embodiment, the first anchor is positioned laterally to the soft tissue and the second and third anchors are positioned beneath the soft tissue. In some embodiments, the lengths of suture are fixedly secured to the anchor(s) positioned beneath the soft tissue prior to insertion of those anchor(s). In one embodiment, the different lengths of suture may be tensioned separately.

In various embodiments, prior to fixedly securing suture to a bone anchor, it can be tensioned. In one embodiment, tensioning is accomplished by manually pulling on the suture such as by a surgeon grasping the suture using an appropriate instrument and then pulling. In one embodiment, the suture may be pressed against the bone anchor to provide leverage for pulling. For example, the suture may be wrapped partly around a proximal portion of the anchor prior to pulling.

Although the invention has been described with reference to embodiments and examples, it should be understood that numerous and various modifications can be made without departing from the spirit of the invention. Accordingly, the invention is limited only by the following claims.

#### What is claimed is:

1. A method of attaching soft tissue to bone, comprising: inserting a first anchor into bone, wherein after insertion, the first anchor is positioned underneath the soft tissue; passing a first length of suture from said first anchor over the soft tissue;

inserting a distal member of a second anchor into bone at a position beyond an edge of the soft tissue, wherein the second anchor comprises said distal member and a proximal member;

after inserting the distal member of the second anchor, tensioning the first length of suture to compress an area of tissue to bone between the edge of the soft tissue and the first anchor; and

after tensioning the first length of suture, moving the proximal member of the second anchor distally towards the distal member of the second anchor, thereby fixedly securing the first length of suture at the second anchor position without tying any knots.

2. The method of claim 1, wherein the first length of suture is attached to the first anchor prior to insertion of the first anchor into bone.

3. The method of claim 1, comprising forming a hole in the bone into which the distal member of the second anchor is inserted.

4. The method of claim 1, wherein the distal member of the second anchor comprises a first proximally facing surface.

5. The method of claim 4, wherein the proximal member of the second anchor has a second distally facing surface facing toward said first surface.

6. The method of claim 5, wherein said proximal member is configured to move relative to said distal member such that it can be positioned in a first configuration wherein said first and second surfaces are spaced apart and be positioned in a second configuration wherein said first and second surfaces are in close proximity.

7. The method of claim 1, wherein the distal member of the second anchor is tapered.

## US 8,100,942 B1

15

8. The method of claim 1, wherein a proximal portion of the distal member of the second anchor comprises a suture gripping structure.

9. The method of claim 1, wherein a proximal end of the distal member of the second anchor comprises a hole opening into a central bore.

10. The method of claim 9, wherein sides of the central bore comprise threads.

11. The method of claim 1, wherein the proximal member of the second anchor is cylindrically shaped.

12. The method of claim 1, wherein a central bore extends through the proximal member of the second anchor.

13. The method of claim 12, wherein inserting the distal member of the second anchor and moving the proximal member of the second anchor distally toward the distal member comprises using an anchor inserter comprising a handle, a tube, and an inner member, wherein the inner member extends through the tube and the central bore in the proximal member of the second anchor and is removably coupled to the distal member of the second anchor.

14. The method of claim 13, wherein the inserter comprises an inner tube and an outer tube, wherein the inner tube extends through the outer tube, and wherein the inner member extends through the inner tube.

15. The method of claim 13, wherein the tube is movable longitudinally relative to the inner member.

16. The method of claim 1, comprising coupling the first length of suture to the second anchor prior to inserting the distal member of the second anchor into bone.

17. The method of claim 1, wherein the tensioning comprises manually pulling on the first length of suture.

18. The method of claim 1, comprising:  
inserting a third anchor into bone, wherein after insertion, the third anchor is positioned underneath the soft tissue;  
passing a second length of suture from said third anchor over the soft issue;  
tensioning the second length of suture independently from the first length of suture; and

16

after tensioning the first and second lengths of suture, moving the proximal member of the second anchor distally towards the distal member of the second anchor, thereby fixedly securing both the first and second lengths of suture at the second anchor position without tying any knots.

19. A method of attaching soft tissue to bone, comprising:  
inserting a first anchor into bone, wherein after insertion, the first anchor is positioned underneath the soft tissue;  
passing a first length of suture from said first anchor over the soft tissue;

coupling the first length of suture to a second anchor, wherein the second anchor comprises a distal member and a proximal member, wherein said proximal member is cylindrically shaped and comprises a central bore extending therethrough;

after coupling the first length of suture to the second anchor, inserting the distal member of the second anchor into bone at a position beyond an edge of the soft tissue;  
after inserting the distal member of the second anchor, tensioning the first length of suture to compress an area of tissue to bone between the edge of the soft tissue and the first anchor; and

after tensioning the first length of suture, moving the proximal member of the second anchor distally towards the distal member of the second anchor, thereby fixedly securing the first length of suture at the second anchor position without tying any knots, wherein inserting the distal member of the second anchor and moving the proximal member of the second anchor distally toward the distal member comprises using an anchor inserter comprising a handle, a tube, and an inner member, wherein the inner member extends through the tube and the central bore in the proximal member of the second anchor and is removably coupled to the distal member of the second anchor.

\* \* \* \* \*

# **EXHIBIT 3**



US008109969B1

(12) **United States Patent**  
**Green et al.**

(10) **Patent No.:** **US 8,109,969 B1**

(45) **Date of Patent:** **\*Feb. 7, 2012**

(54) **SYSTEM AND METHOD FOR ATTACHING  
SOFT TISSUE TO BONE**

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(73) Assignee: **KFx Medical Corporation**, Carlsbad,  
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(\*) Notice: Subject to any disclaimer, the term of this  
patent is extended or adjusted under 35  
U.S.C. 154(b) by 0 days.

This patent is subject to a terminal dis-  
claimer.

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Court, Southern District of California, Sep. 23, 2011, Los Angeles,  
USA.

(21) Appl. No.: **13/245,622**

(22) Filed: **Sep. 26, 2011**

(Continued)

#### Related U.S. Application Data

(60) Continuation of application No. 12/549,105, filed on  
Aug. 27, 2009, which is a division of application No.  
11/143,007, filed on Jun. 1, 2005, now Pat. No.  
7,585,311.

(60) Provisional application No. 60/576,477, filed on Jun.  
2, 2004, provisional application No. 60/610,924, filed  
on Sep. 17, 2004, provisional application No.  
60/634,174, filed on Dec. 7, 2004.

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*Assistant Examiner* — Gregory Anderson

(74) *Attorney, Agent, or Firm* — Knobbe Martens Olson &  
Bear LLP

(51) **Int. Cl.**  
**A61B 17/04** (2006.01)

(52) **U.S. Cl.** ..... **606/232; 606/300**

(58) **Field of Classification Search** ..... **606/72,**  
**606/75, 78, 219, 224, 232, 300-331**

See application file for complete search history.

(57) **ABSTRACT**

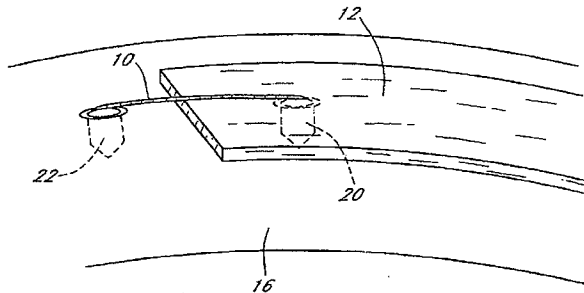
Disclosed herein are methods and devices for securing soft  
tissue to a rigid material such as bone. A bone anchor is  
described that comprises a base and a top such that suture  
material may be compressed between surfaces on the base  
and top to secure the suture to the anchor. Also described is an  
insertor that can be used to insert the bone anchor into bone  
and move the anchor top relative to the anchor base to clamp  
suture material there between. Also described is a soft-tissue  
and bone piercing anchor and associated insertor. Methods  
are described that allow use of the bone anchors to provide  
multiple lengths of suture material to compress a large area of  
soft tissue against bone.

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**17 Claims, 24 Drawing Sheets**





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U.S. Patent

Feb. 7, 2012

Sheet 1 of 24

US 8,109,969 B1

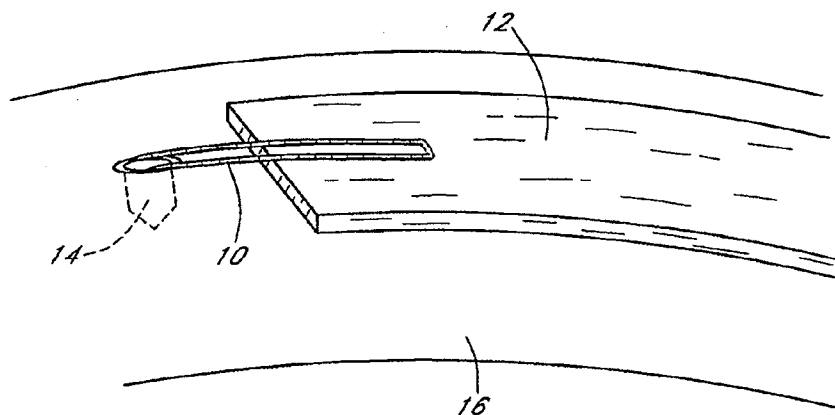


FIG. 1

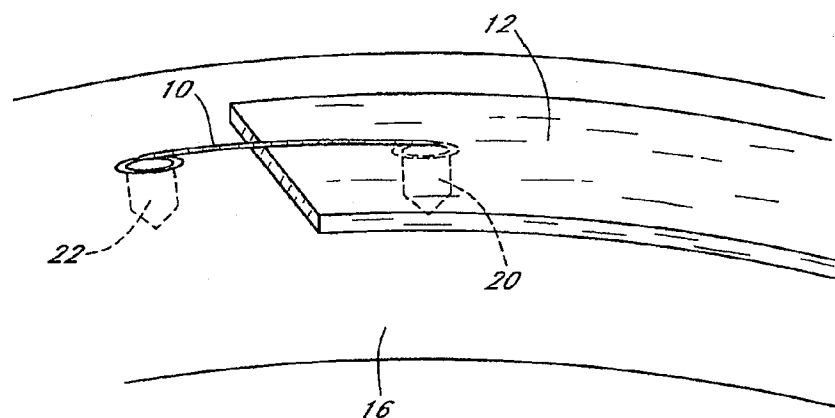


FIG. 2

U.S. Patent

Feb. 7, 2012

Sheet 2 of 24

US 8,109,969 B1

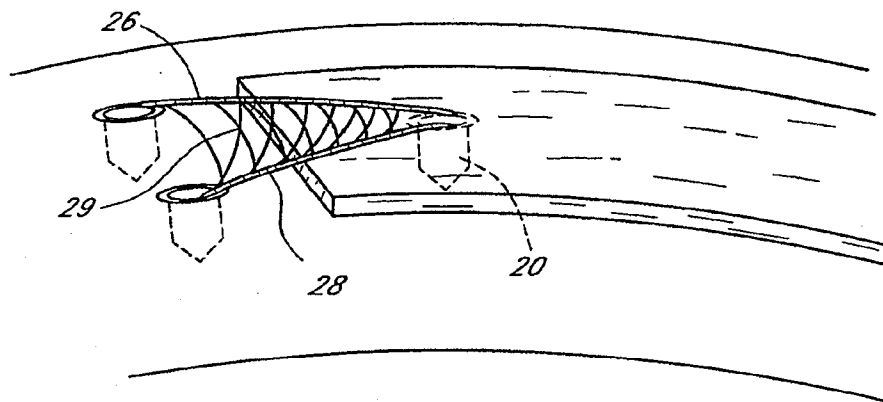


FIG. 3A

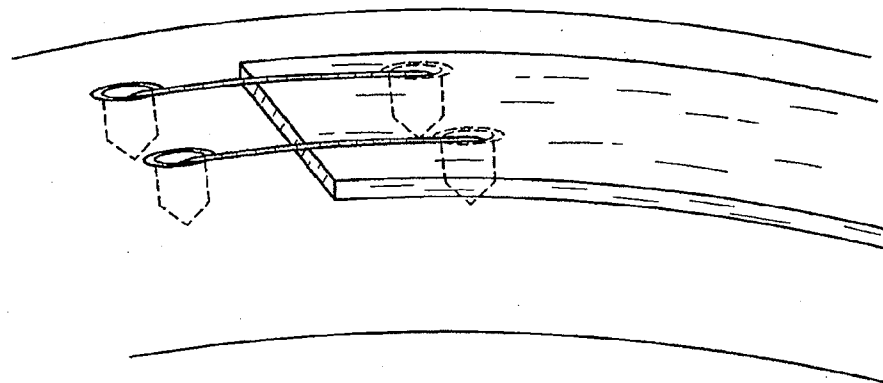


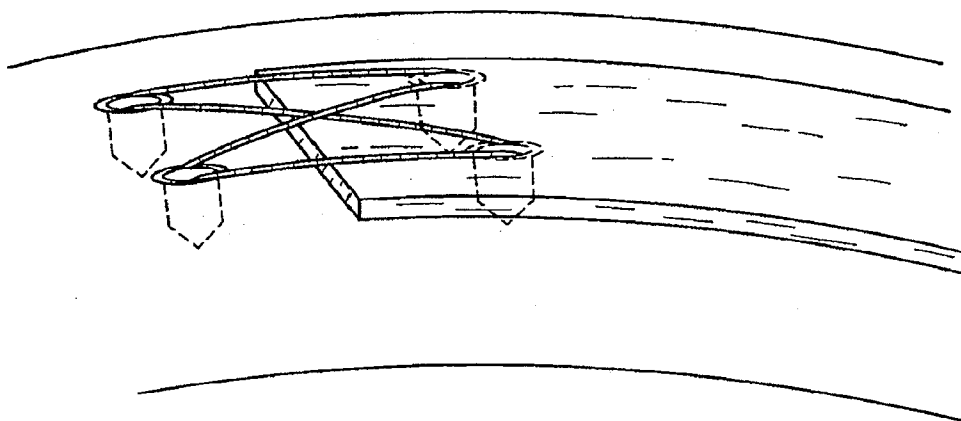
FIG. 3B

**U.S. Patent**

**Feb. 7, 2012**

**Sheet 3 of 24**

**US 8,109,969 B1**



**FIG. 3C**

U.S. Patent

Feb. 7, 2012

Sheet 4 of 24

US 8,109,969 B1

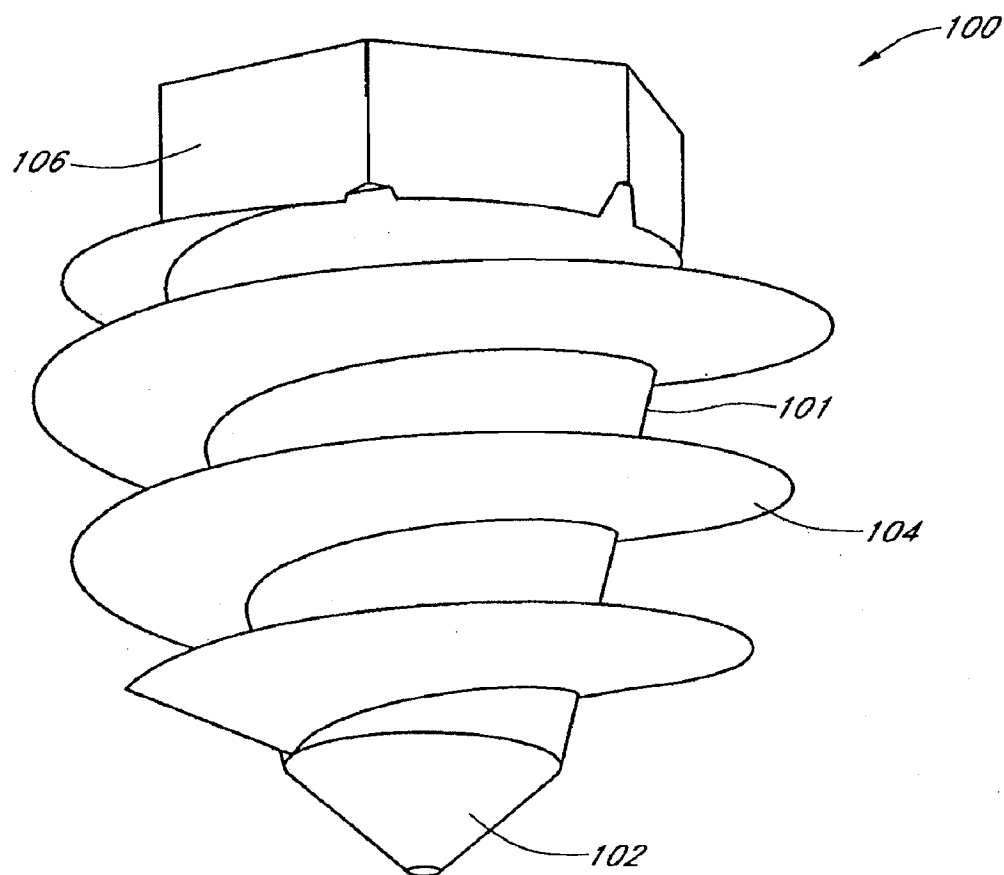


FIG. 4A

U.S. Patent

Feb. 7, 2012

Sheet 5 of 24

US 8,109,969 B1

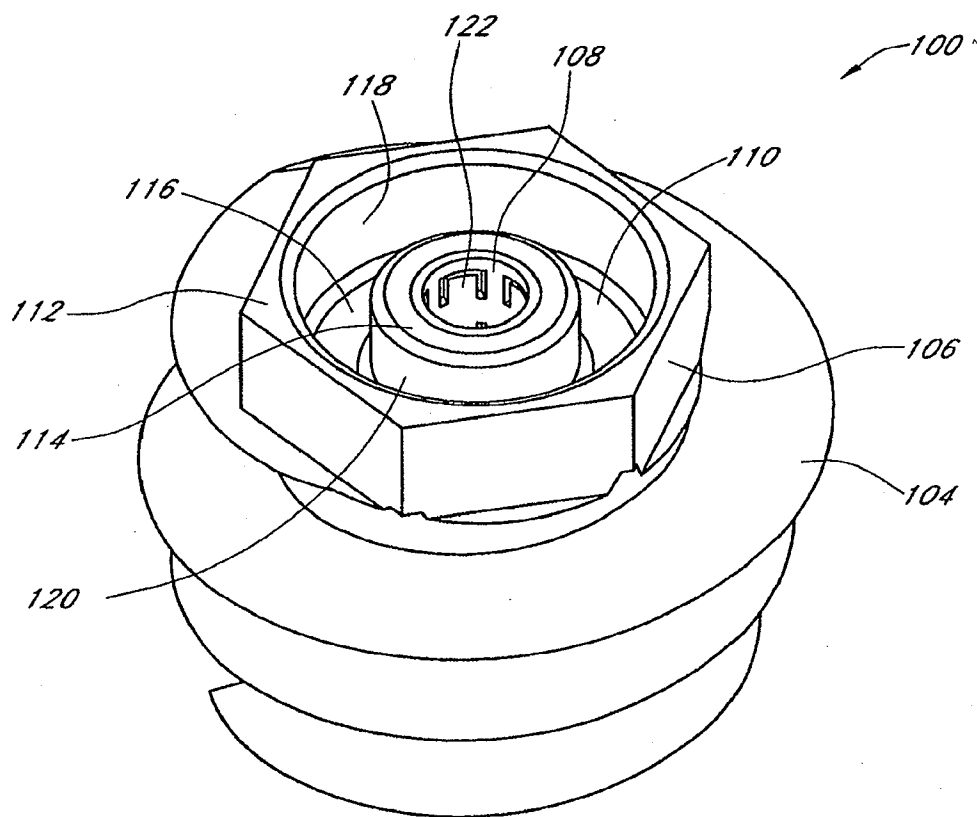


FIG. 4B

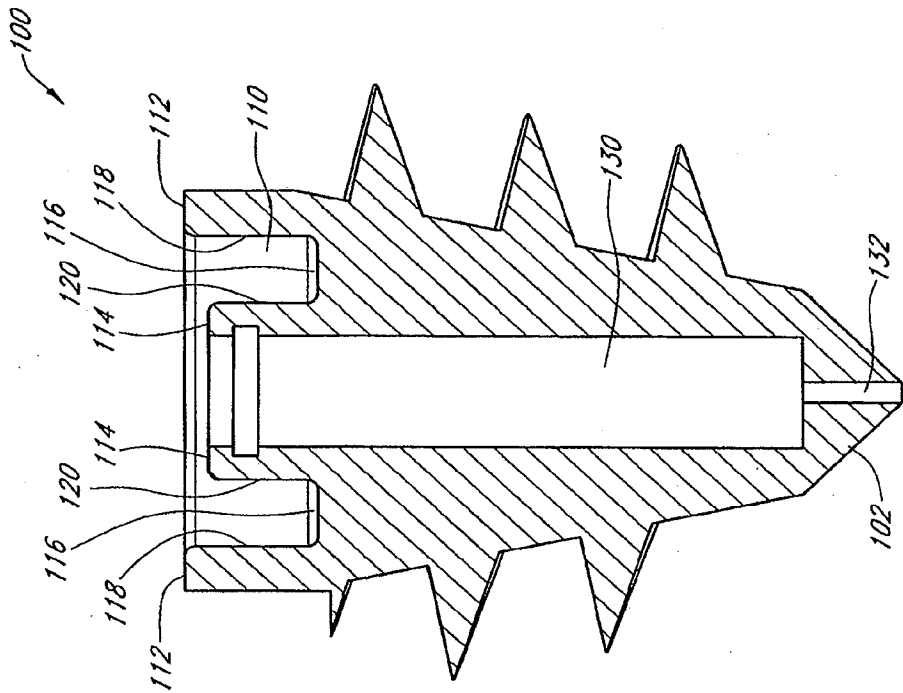


FIG. 4D

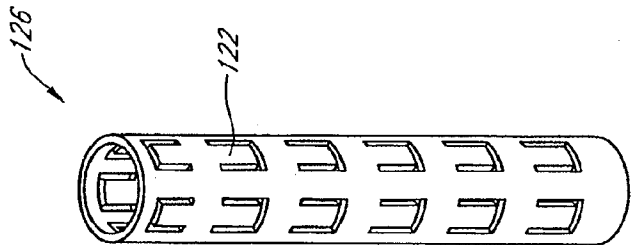


FIG. 4C



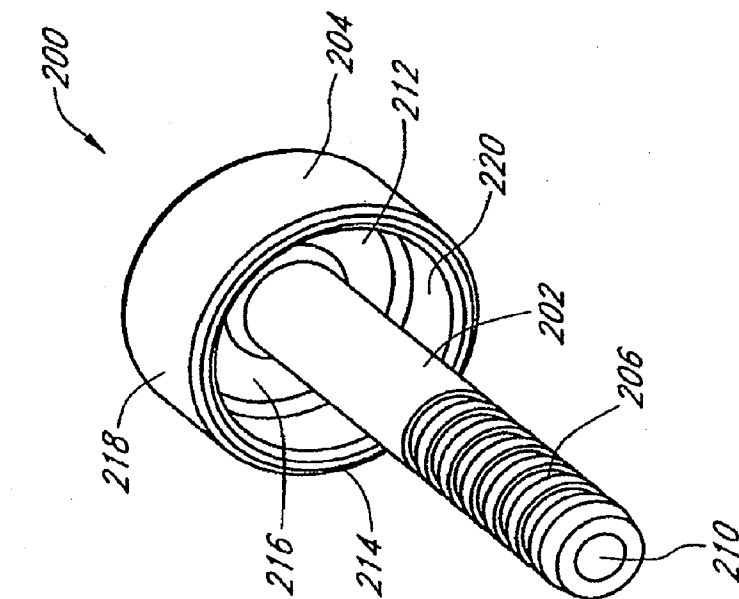


FIG. 5B

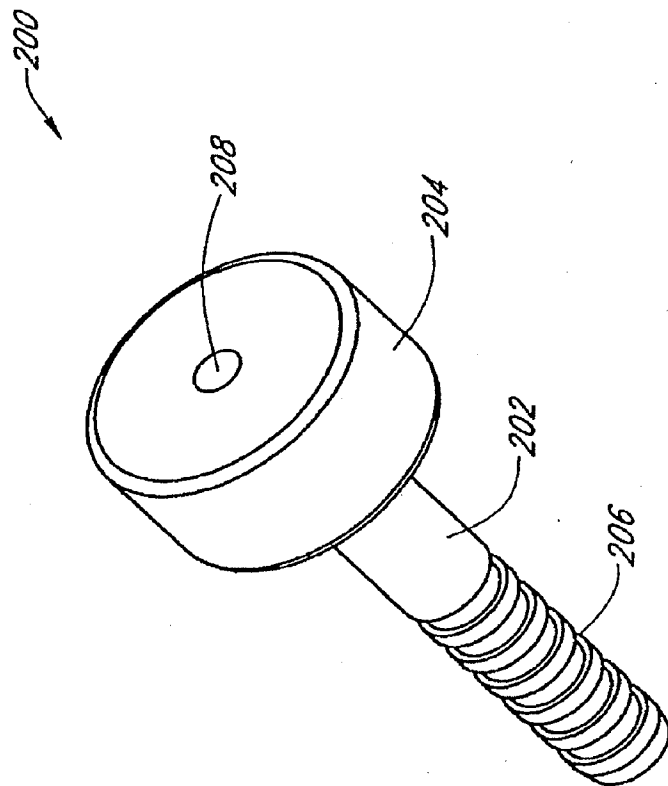


FIG. 5A

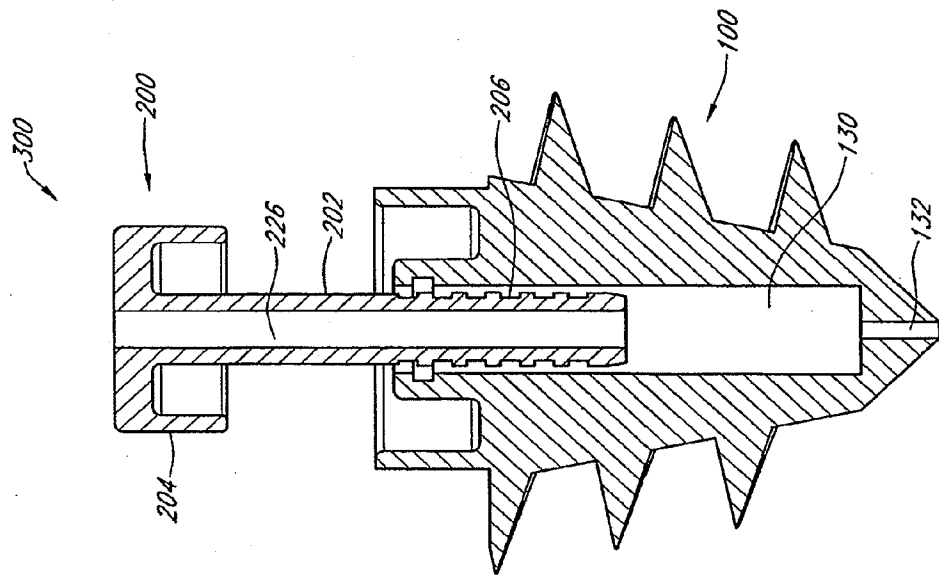


FIG. 6A

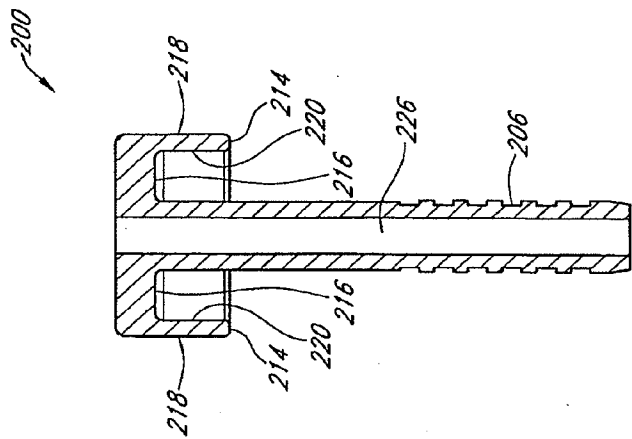


FIG. 5C

U.S. Patent

Feb. 7, 2012

Sheet 9 of 24

US 8,109,969 B1

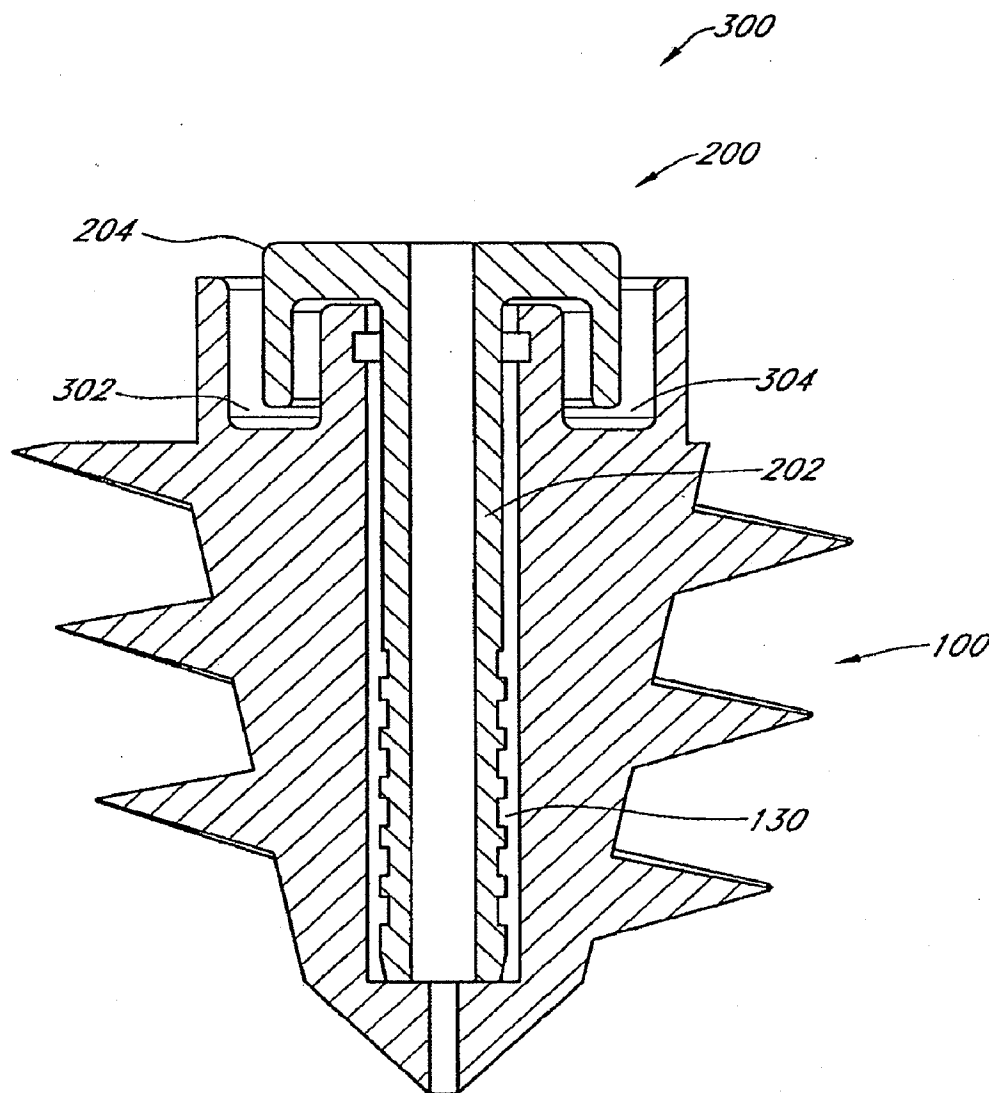
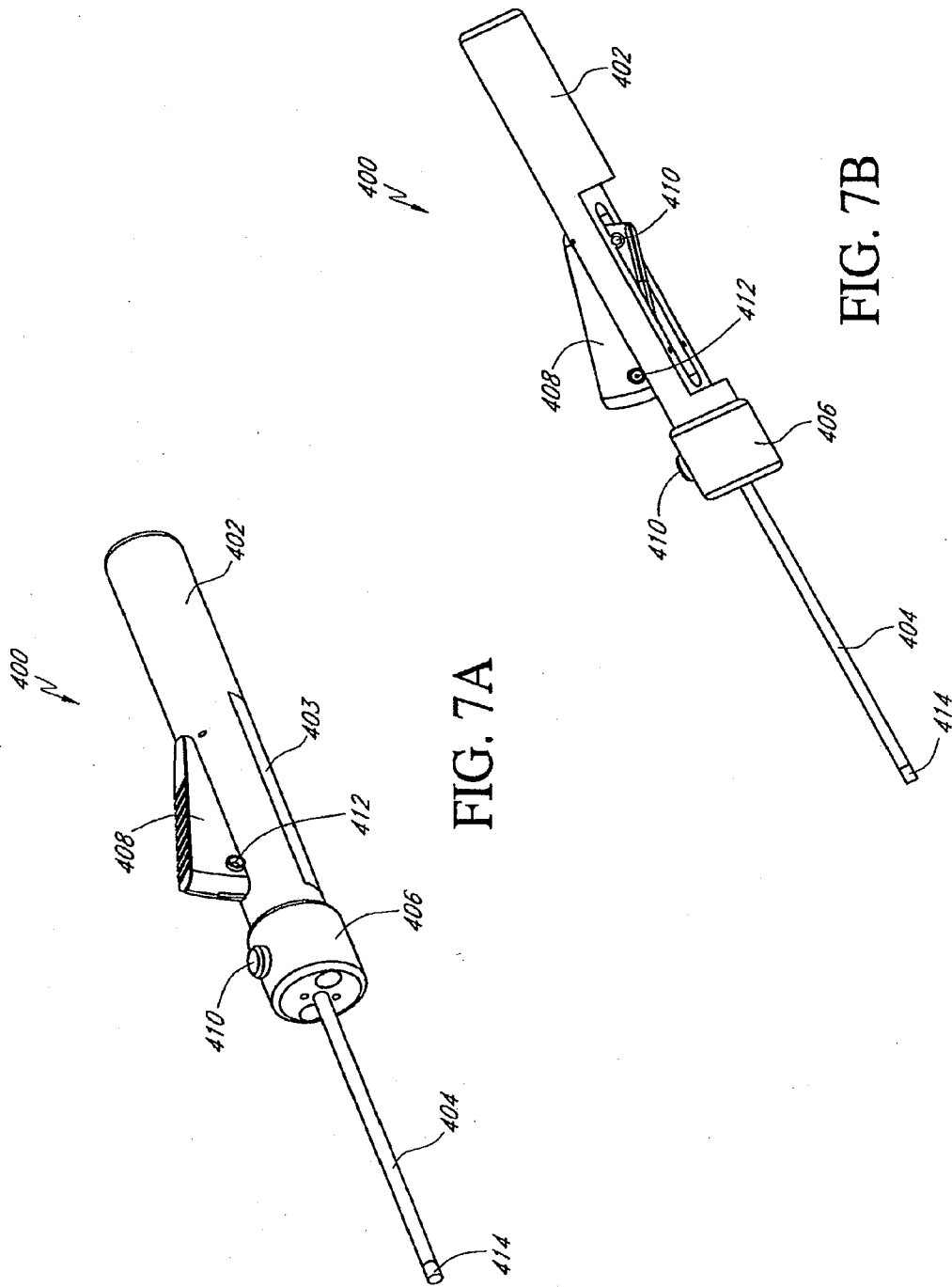


FIG. 6B



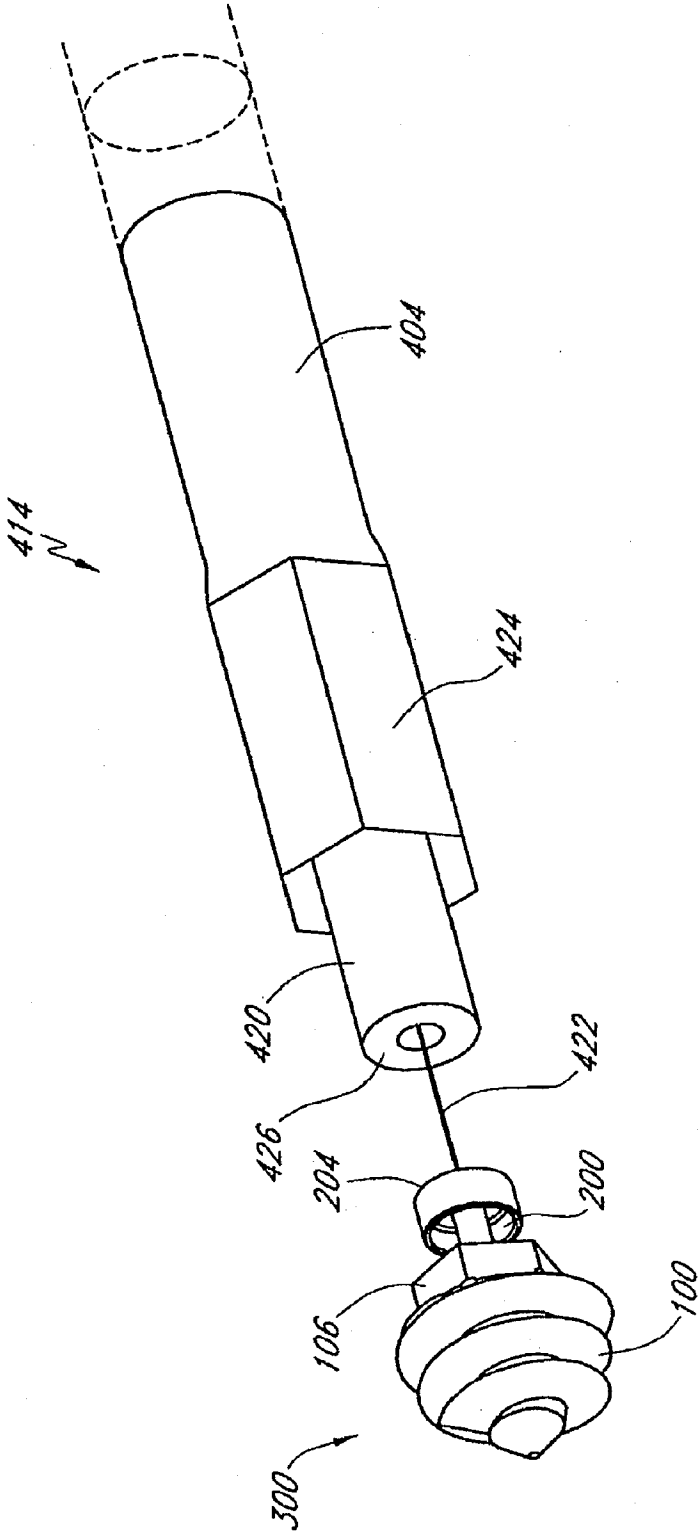


FIG. 8

U.S. Patent

Feb. 7, 2012

Sheet 12 of 24

US 8,109,969 B1

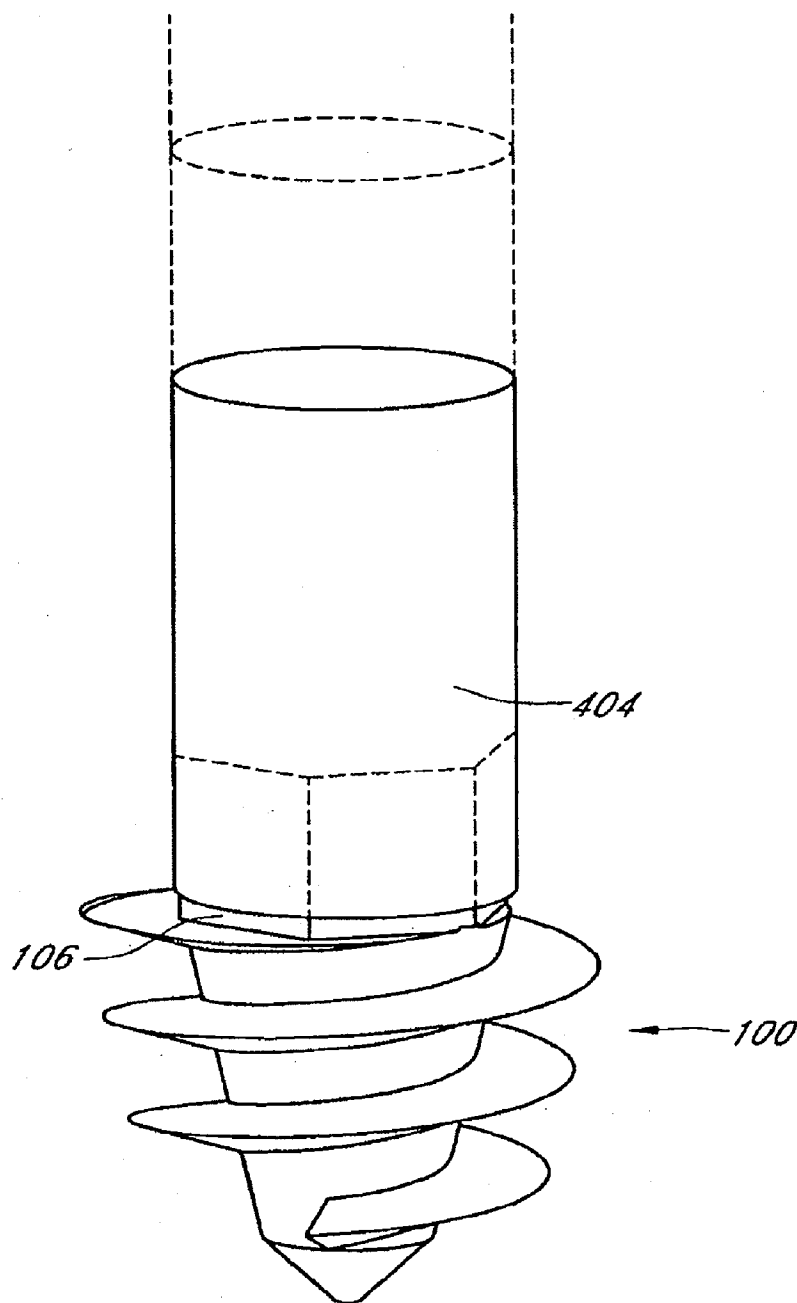


FIG. 9A

U.S. Patent

Feb. 7, 2012

Sheet 13 of 24

US 8,109,969 B1

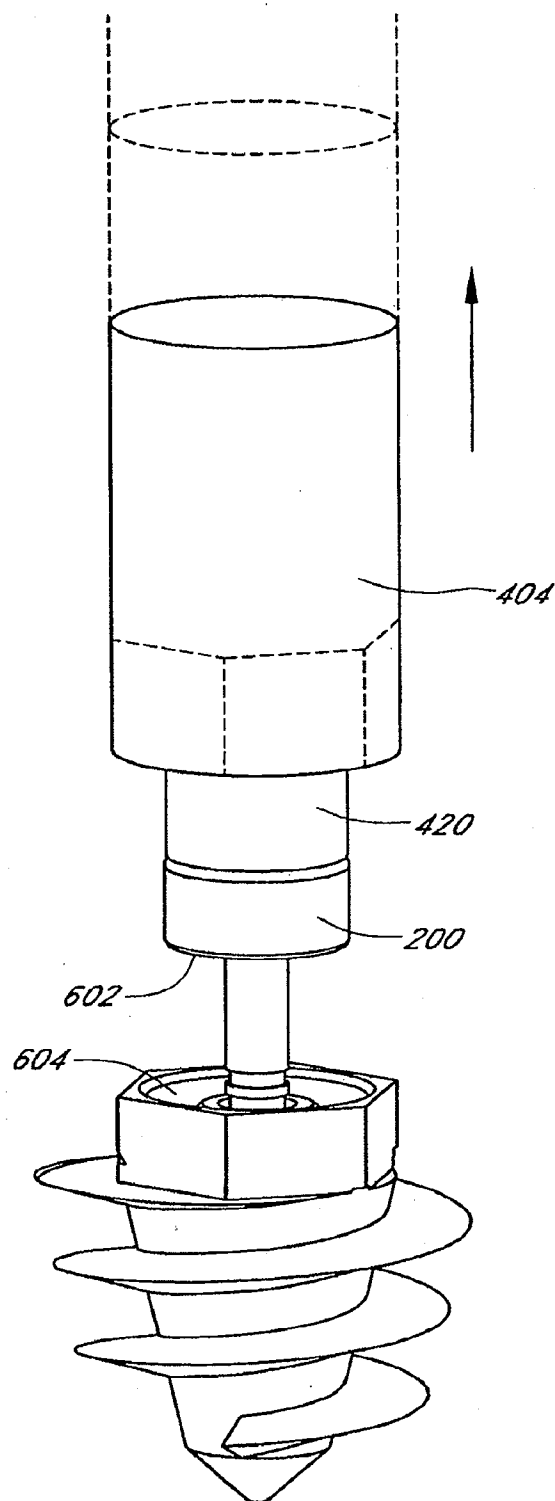


FIG. 9B

U.S. Patent

Feb. 7, 2012

Sheet 14 of 24

US 8,109,969 B1

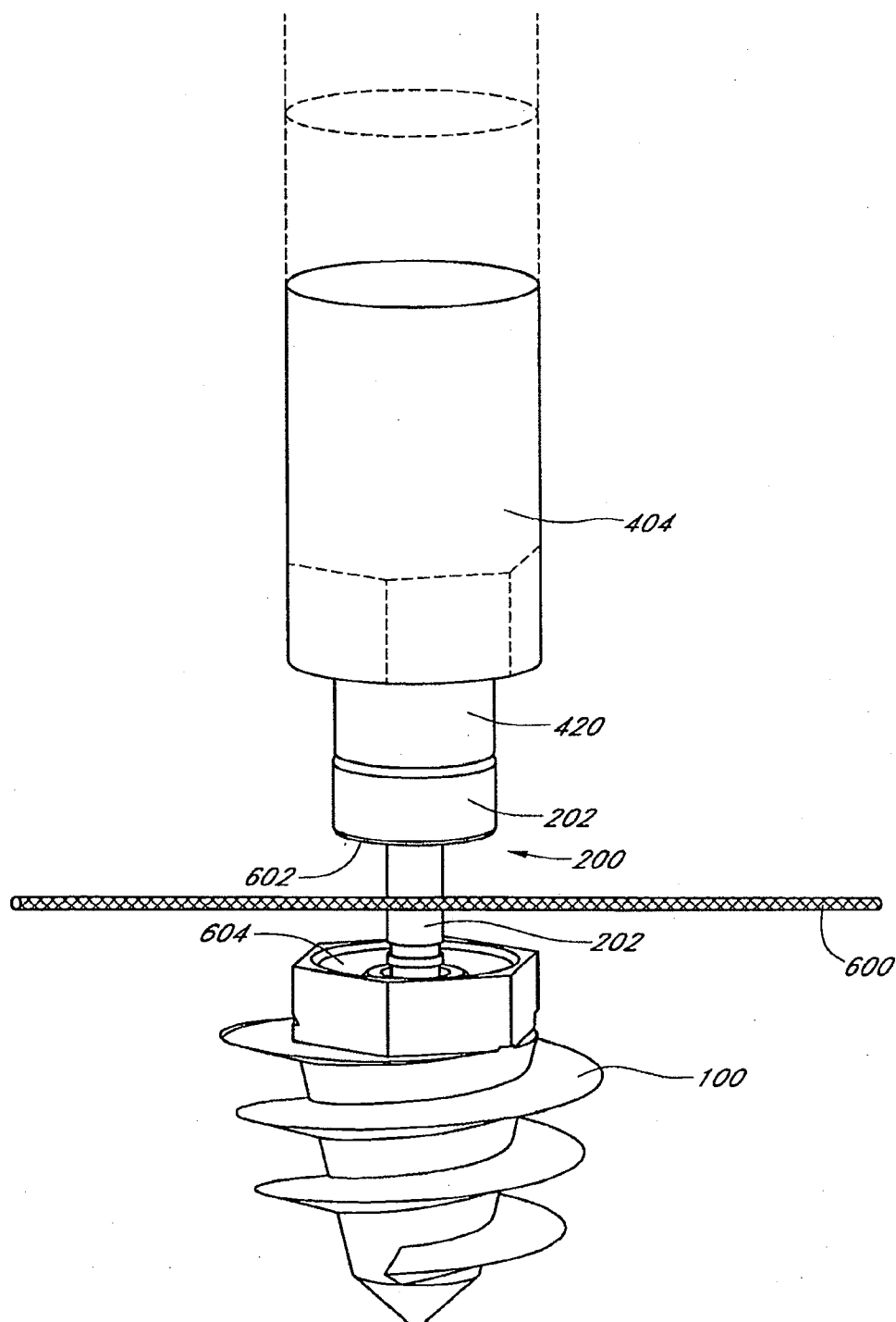


FIG. 9C



U.S. Patent

Feb. 7, 2012

Sheet 15 of 24

US 8,109,969 B1

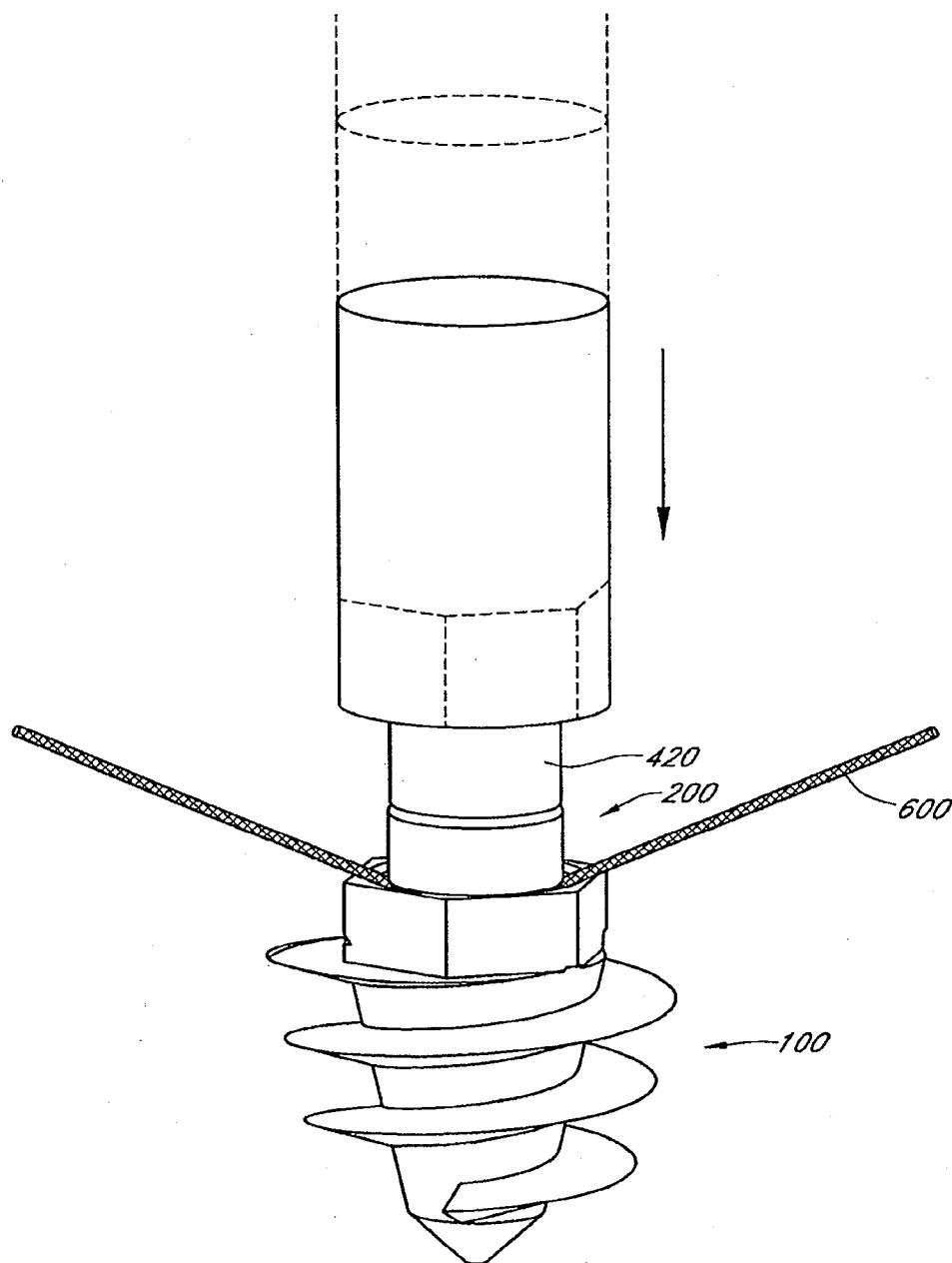


FIG. 9D

U.S. Patent

Feb. 7, 2012

Sheet 16 of 24

US 8,109,969 B1

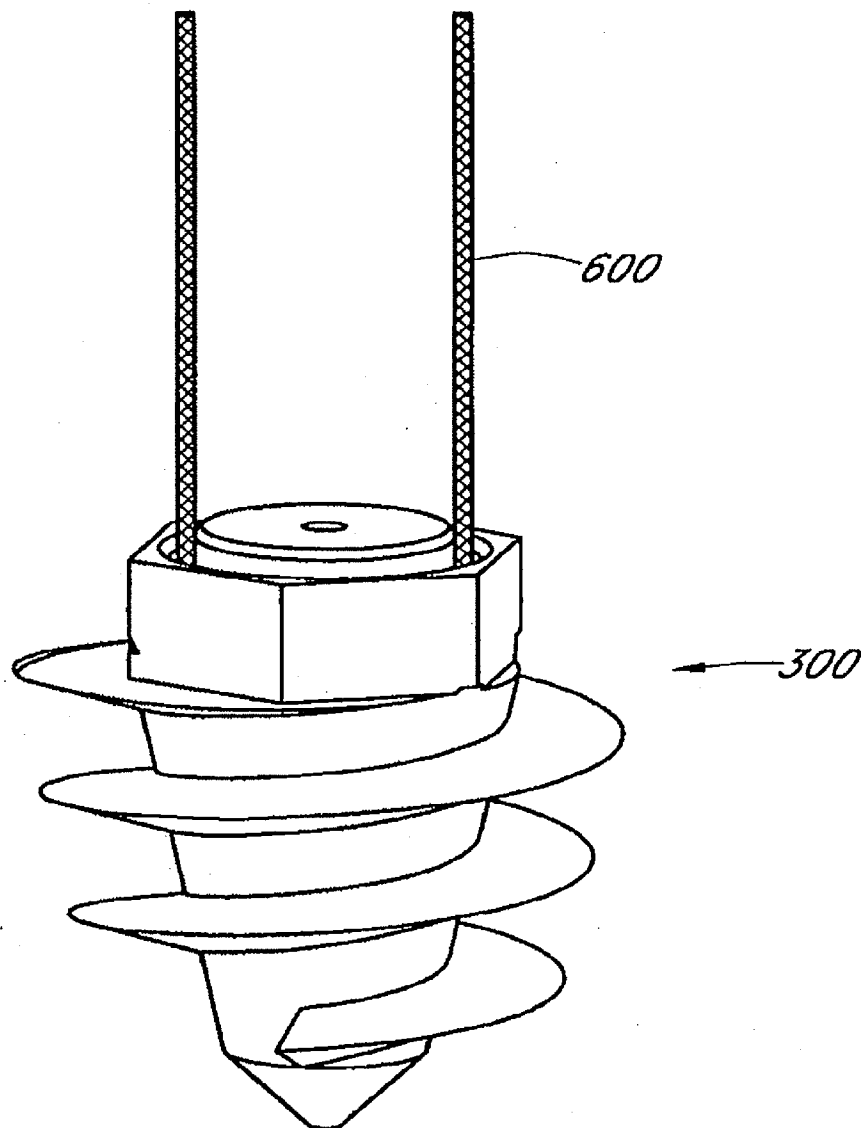


FIG. 9E

U.S. Patent

Feb. 7, 2012

Sheet 17 of 24

US 8,109,969 B1

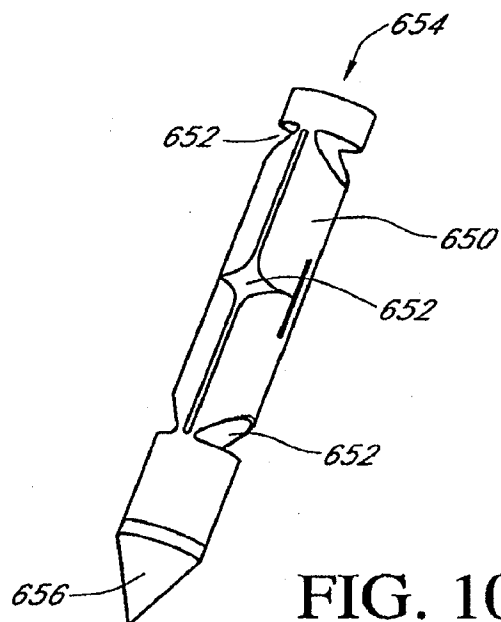


FIG. 10A

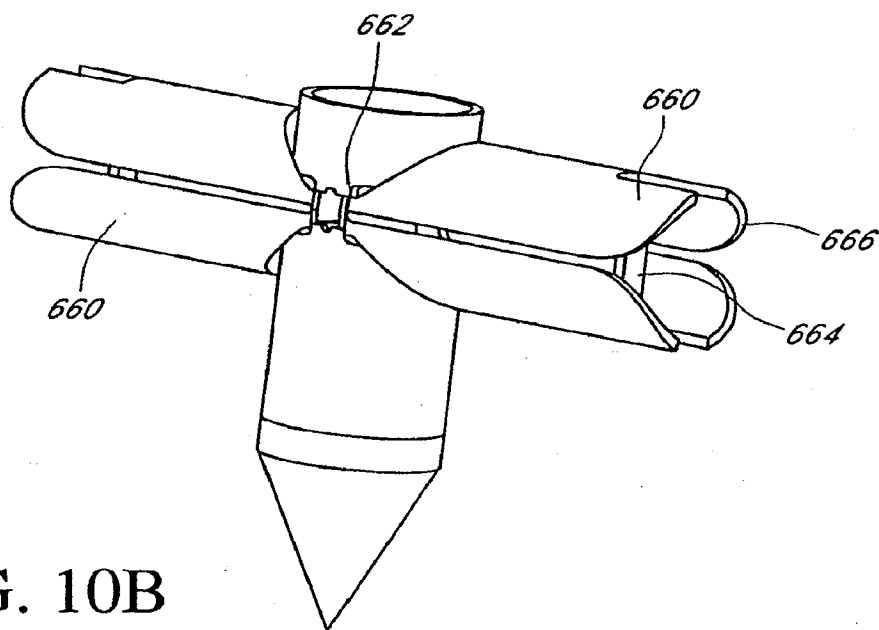


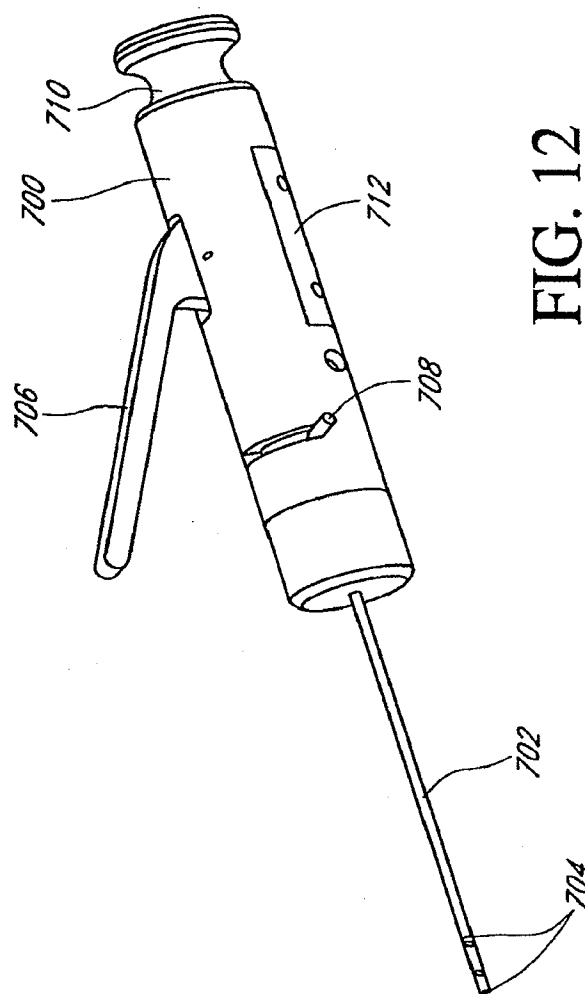
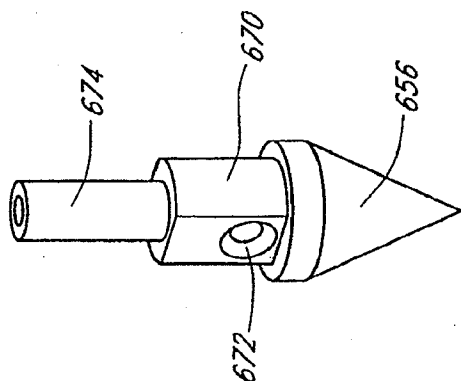
FIG. 10B

U.S. Patent

Feb. 7, 2012

Sheet 18 of 24

US 8,109,969 B1



U.S. Patent

Feb. 7, 2012

Sheet 19 of 24

US 8,109,969 B1

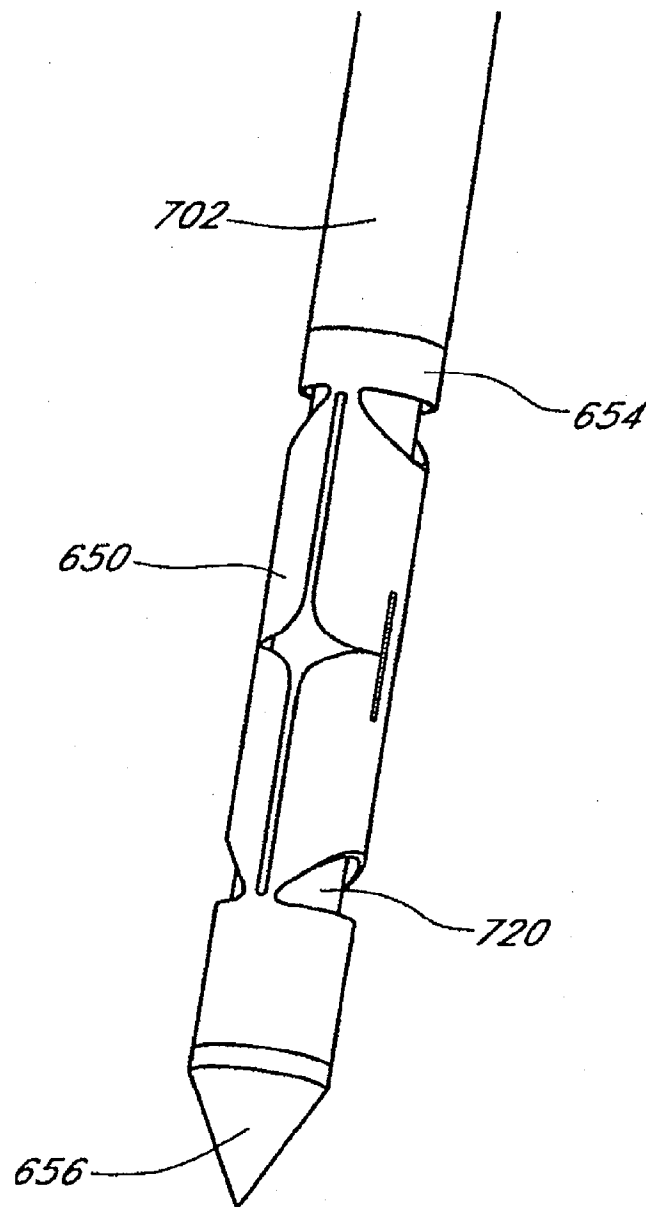


FIG. 13

U.S. Patent

Feb. 7, 2012

Sheet 20 of 24

US 8,109,969 B1

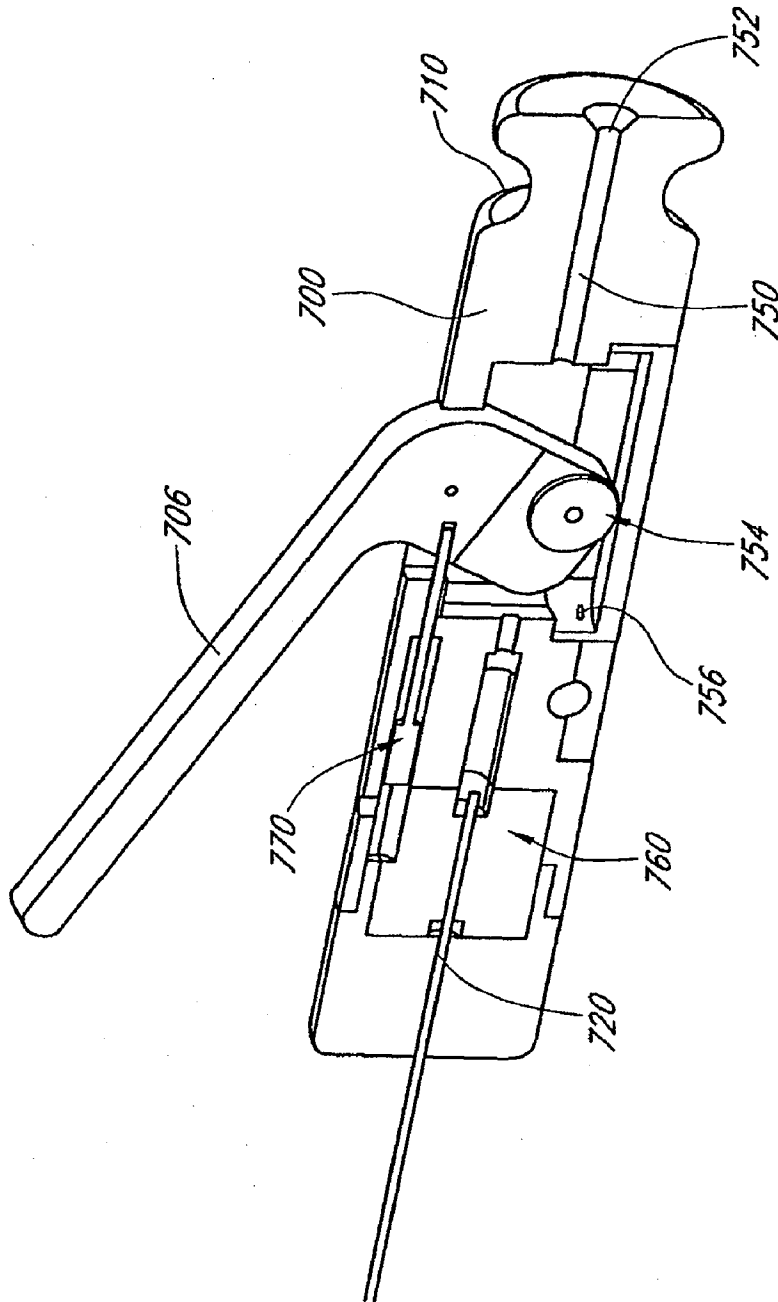


FIG. 14

U.S. Patent

Feb. 7, 2012

Sheet 21 of 24

US 8,109,969 B1

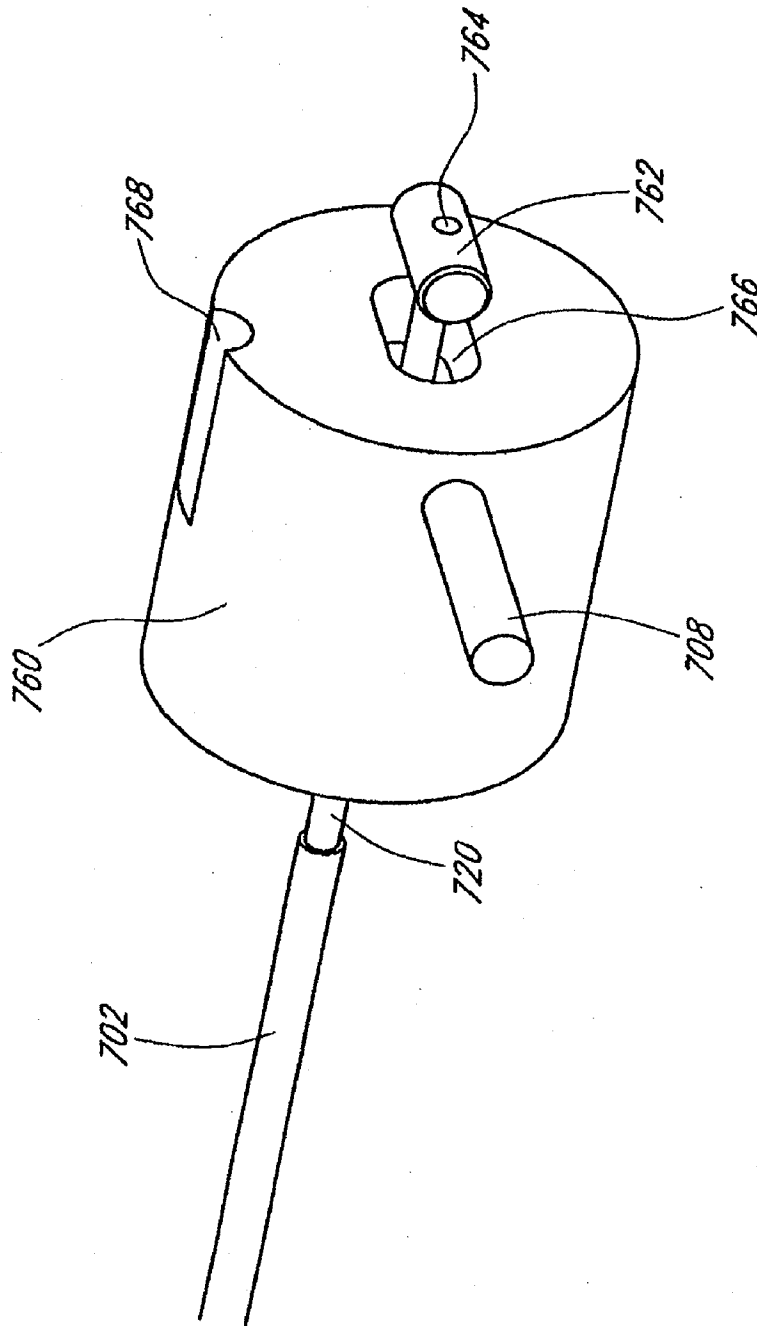


FIG. 15

U.S. Patent

Feb. 7, 2012

Sheet 22 of 24

US 8,109,969 B1

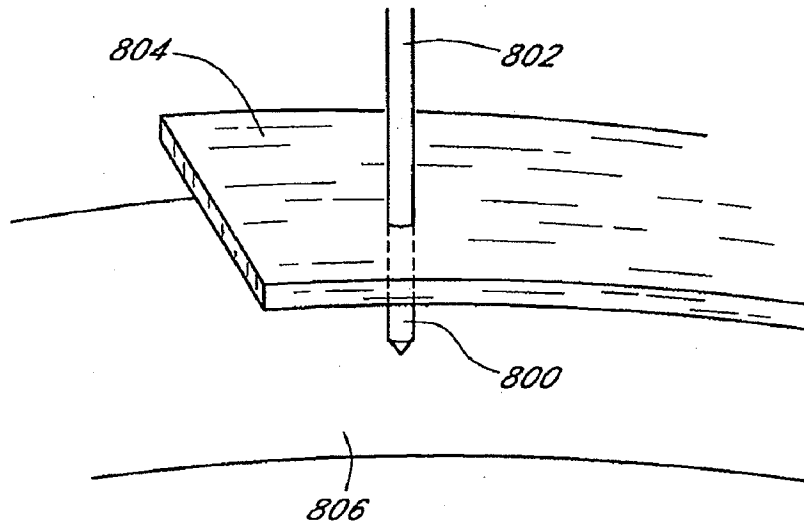


FIG. 16A

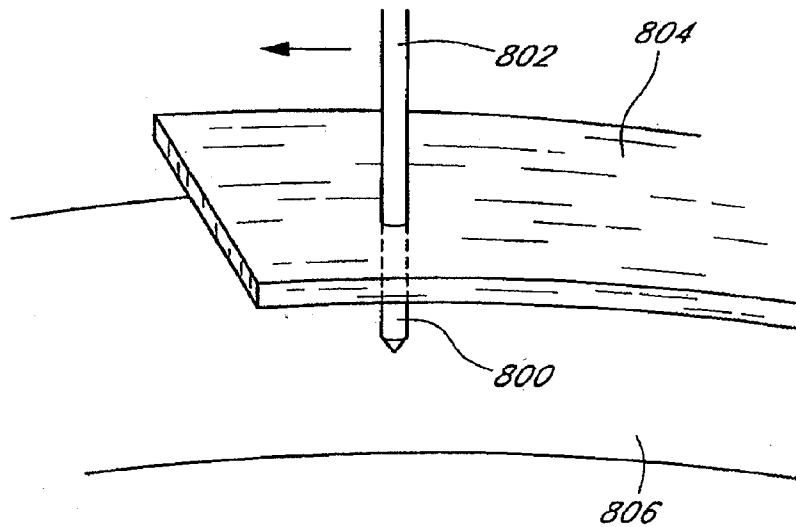


FIG. 16B



U.S. Patent

Feb. 7, 2012

Sheet 23 of 24

US 8,109,969 B1

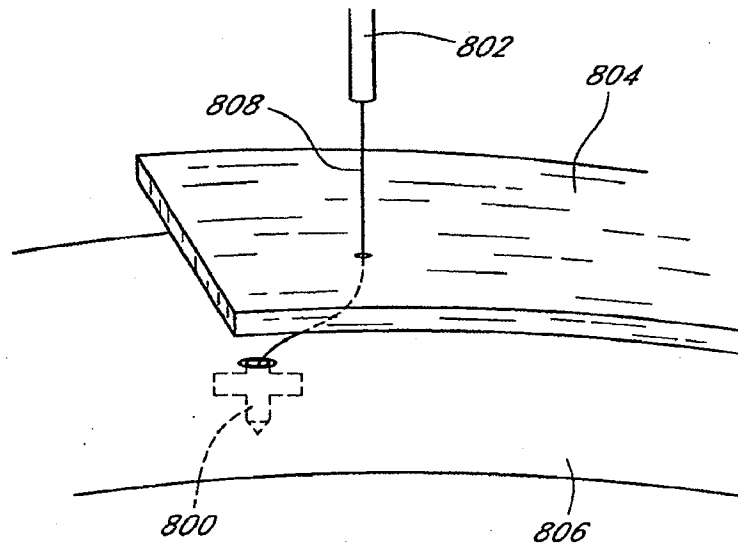


FIG. 16C

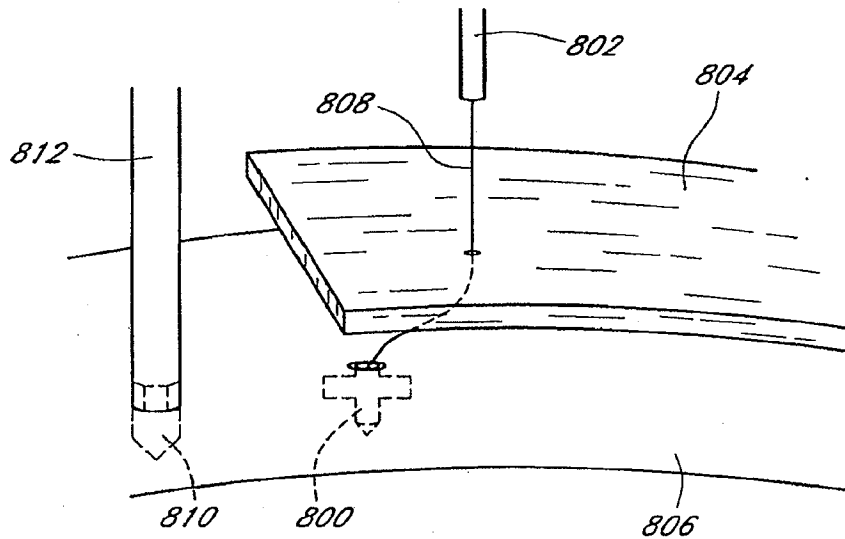


FIG. 16D

U.S. Patent

Feb. 7, 2012

Sheet 24 of 24

US 8,109,969 B1

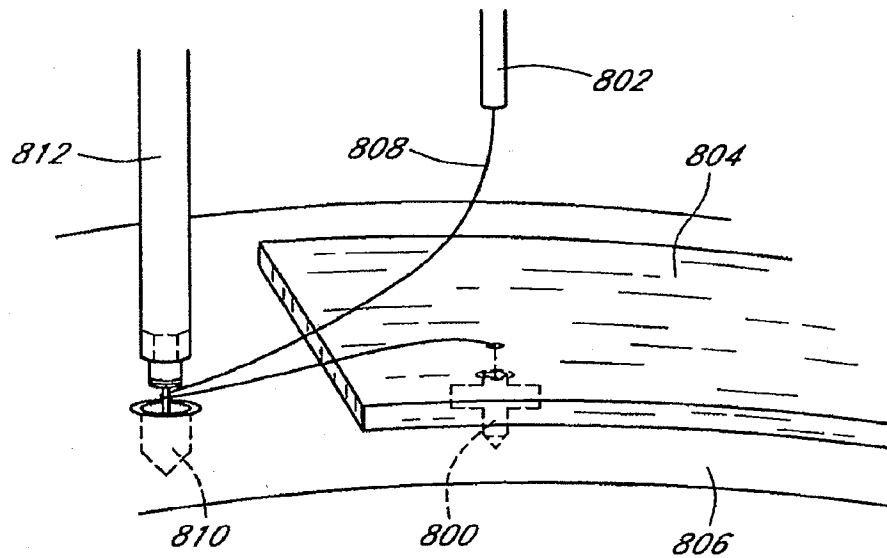


FIG. 16E

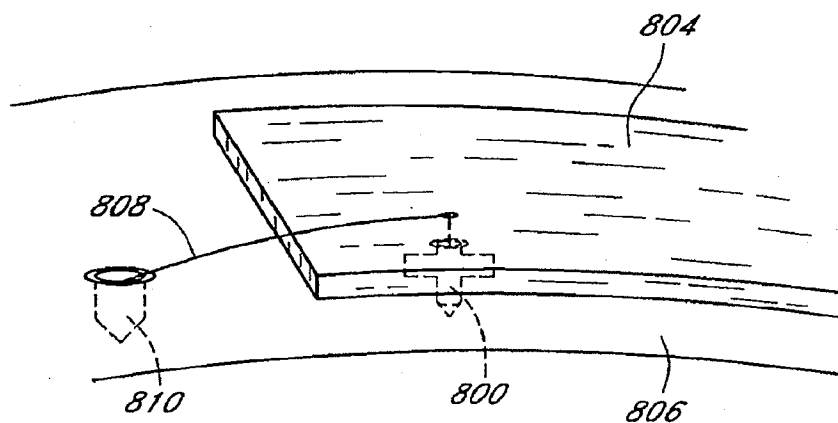


FIG. 16F

US 8,109,969 B1

1

## SYSTEM AND METHOD FOR ATTACHING SOFT TISSUE TO BONE

### RELATED APPLICATIONS

This application is a continuation of U.S. application Ser. No. 12/549,105, filed Aug. 27, 2009, which is a divisional of U.S. application Ser. No. 11/143,007, now U.S. Pat. No. 7,585,311, filed Jun. 1, 2005, which claims priority to U.S. Provisional Application Nos. 60/576,477, filed on Jun. 2, 2004; 60/610,924, filed on Sep. 17, 2004; and 60/634,174, filed on Dec. 7, 2004; all of which are incorporated herein by reference in their entirety.

### BACKGROUND OF THE INVENTION

#### 1. Field of the Invention

The present invention relates to medical devices and procedures. More particularly, the present invention relates to devices and methods for securing soft tissue to a rigid material such as bone.

#### 2. Description of the Related Art

There are several medical procedures where a surgeon needs to attach soft tissue such as tendons or other soft connective tissue to bone. One common example is a torn rotator cuff, where the supraspinatus tendon has separated from the humerus causing pain and loss of ability to elevate and externally rotate the arm. To repair a torn rotator cuff, typically a surgical procedure is used to suture the torn tendon to the bone using a variety of methods. Some procedures utilize large incisions and involve complete detachment of the deltoid muscle from the acromion. Small diameter holes are made in the bone for passing suture material through the bone to secure the tendon. Such large incision procedures are traumatic, causing prolonged pain and recovery time. Other procedures make small incisions and use arthroscopic techniques to attach sutures using either small diameter holes or a bone anchor. However, it is difficult to manipulate sutures within the surgical site using arthroscopic techniques. In addition, when knot tying is used to secure the suture to a bone anchor, it is difficult to properly adjust the tension of the suture while tightening the knot. Similarly, when the suture is attached to a bone anchor prior to insertion of the anchor into the bone, it is difficult to judge the appropriate point of attachment so that the suture will be properly tensioned upon insertion of the bone anchor into the bone. Thus, there is a need for methods and devices that allow easy arthroscopic attachment of a suture to a bone anchor after the anchor is inserted into the bone without the use of knot tying.

### SUMMARY OF THE INVENTION

The present invention is particularly suited for use in arthroscopic procedures, including but not limited to rotator cuff surgery. More broadly, it can be used in any procedure in which it is desired to fix a suture to a solid object without tying of knots, including not only arthroscopic procedures, but also open surgery, and can be used for such diverse purposes as bladder neck suspension, tendon and ligament affixation or repair, prosthetic attachment, and rotator cuff repair.

In one embodiment, the invention includes an anchor for securing a suture to bone, including an anchor base adapted to be securely fixed into the bone and a suture securing mechanism coupled to the anchor base and positioned proximally relative to the anchor base, the mechanism adapted to receive and secure a suture moved laterally into the

2

In another embodiment, the invention includes an anchor for securing a suture to bone, including an anchor base adapted to be securely fixed into the bone, a first surface coupled to the anchor base and positioned proximally relative to the anchor base, and a second surface coupled to the anchor base and positioned proximally relative to the anchor base, wherein the first and second surfaces are adapted to be relatively positioned in at least two configurations, one of the configurations such that a gap is present between the first and second surfaces so that the suture can be positioned between the first and second surfaces by moving the suture laterally into the gap, and the other of the configurations such that the first and second surfaces are in close proximity so that the suture can be securely clamped between the first and second surfaces.

In another embodiment, the invention includes a method of attaching soft tissue to bone, including passing a length of suture over the soft tissue, inserting an anchor into the bone, and securing the length of suture to the anchor after the inserting without passing an end of the length of suture through any aperture in the anchor and without tying any knots.

In another embodiment, the invention includes a method of attaching soft tissue to bone, including inserting a first anchor through the soft tissue, wherein the first anchor comprises a length of suture fixedly secured to the first anchor prior to insertion, inserting the first anchor into the bone, passing the length of suture over the soft tissue, and fixedly securing, after the passing, the length of suture to a second anchor.

In another embodiment, the invention includes a method of attaching soft tissue to bone, the soft tissue comprising a first surface adjacent to the bone's surface and a second surface opposite the first surface, the method including inserting a first portion of a length of suture into the second surface of the soft tissue, passing a second portion of the length of suture over the second surface of the soft tissue, inserting a first anchor with no suture coupled thereto into the bone, and fixedly securing the length of suture to the inserted first anchor, with the proviso that no part of the first portion of the length of suture is passed out of the second surface of the soft tissue.

In another embodiment, the invention includes a method of attaching soft tissue to bone, including inserting a first anchor with a length of suture pre-coupled thereto through the soft tissue, inserting the first anchor into the bone, inserting a second anchor with no suture coupled thereto into bone, passing the length of suture over the soft tissue, and fixedly securing the length of suture to the inserted second anchor.

In another embodiment, the invention includes a method of attaching soft tissue to bone, the method including inserting a first, second, and third anchor into the bone, fixedly securing a first length of suture over the soft tissue to the first and second anchors, and fixedly securing a second length of suture over the soft tissue to the first and third anchors.

In another embodiment, the invention includes an anchor for securing a suture to bone, the anchor including an anchor base adapted to be securely fixed into the bone, the anchor base comprising a first proximal surface and an anchor top, the anchor top comprising a distal member coupled to the anchor base and a first proximal member comprising a first distal surface, wherein the anchor top is adapted to couple to the anchor base in at least two configurations, one of the configurations such that the first distal surface is above the bone's surface when the anchor base is securely fixed into the bone, such that a suture can be freely passed between the first proximal and first distal surfaces above the bone's surface, and the other of the configurations such that the first distal

US 8,109,969 B1

3

surface is in close proximity to the first proximal surface, such that a suture can be securely clamped between the first proximal and first distal surfaces.

In another embodiment, the invention includes an anchor for securing a suture to bone, the anchor including a substantially hollow cylinder comprising an open end and comprising a portion of its walls cut in such a manner so as to allow the cylinder to deform under stress and form lateral protrusions, a substantially pointed tip coupled to the cylinder opposite the open end, wherein the pointed tip is adapted to pierce the bone, and a suture receiver coupled to the pointed tip and positioned within the substantially hollow cylinder so that a suture may be attached to the suture receiver and extend through the cylinder and out of the open end.

#### BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 depicts attaching soft tissue to bone using a single bone anchor and a stitch.

FIG. 2 depicts attaching soft tissue to bone using a two bone anchors with a suture stretched there between.

FIGS. 3A-3C depict various geometries of bone anchors and suture patterns for attaching soft tissue to bone.

FIGS. 4A-4D depicts the base of a two-part suture anchor that can be inserted into bone.

FIGS. 5A-5C depicts the top of a two-part suture anchor.

FIGS. 6A and 6B depict the suture anchor top of FIGS. 5A-5C inserted into the suture anchor bottom of FIGS. 4A-4D.

FIGS. 7A and 7B depict a suture anchor inserter.

FIG. 8 depicts components on a suture anchor inserter for attaching to bone and manipulating a suture anchor.

FIGS. 9A-9E depicts manipulation of a suture anchor using a suture anchor inserter to insert the suture anchor into bone and attach suture material to the suture anchor.

FIGS. 10A and 10B depict a piercing bone anchor in an un-deployed (FIG. 10A) and deployed (FIG. 10B) state.

FIG. 11 depicts a piercing bone anchor tip.

FIG. 12 depicts an anchor inserter for inserting a piercing bone anchor.

FIG. 13 depicts the interface between a piercing bone anchor and an anchor inserter.

FIG. 14 is a cut-away view of a bone anchor inserter.

FIG. 15 depicts a safety switch mechanism for a bone anchor inserter.

FIGS. 16A-16F depict a method for attaching soft-tissue to bone using a piercing bone anchor and a suture capturing anchor.

#### DETAILED DESCRIPTION OF THE CERTAIN EMBODIMENTS

In various embodiments, soft tissue may be attached to bone utilizing one or more bone anchors with suture attached thereto. As used herein, "suture" refers to any flexible structure that can be stretched between two or more anchors and includes, without limitation, traditional suture material, single or multiple stranded threads, or a mesh structure. In some embodiments, suture is passed over the top of the soft tissue so that the suture can press the soft tissue against the bone. In one embodiment, a length of suture is attached to a single bone anchor. One non-limiting example, depicted in FIG. 1, includes stitching the suture 10 to the soft tissue 12, such as by an incline mattress stitch, and then securing the suture 10 to the single bone anchor 14 that is inserted into the bone 16. However, in other embodiments, a length of suture is attached to multiple bone anchors. The use of multiple bone

4

anchors increases the footprint over which the suture material presses the soft tissue against bone. One non-limiting example, depicted in FIG. 2, includes two bone anchors. One anchor 20 is positioned in a medial location underneath the soft tissue 12 and a second anchor 22 is positioned lateral to the soft tissue 12. The suture 10 is attached to both anchors.

In one embodiment, the suture 10 is attached to the lateral bone anchor 22 only after the medial bone anchor 20 is inserted and the suture 10 is passed over the soft tissue 12. In one embodiment, the suture 10 is attached to the medial bone anchor 20 prior to insertion of the medial bone anchor 20. Thus, in this embodiment, the surgeon does not need to pass the suture through the soft tissue 12 from beneath the soft tissue 12. In one embodiment, the procedure involves inserting the medial bone anchor 20 with suture 10 pre-attached through the soft tissue 12. The medial bone anchor 20 may then be moved laterally relative to the bone 16 in order to pull the soft tissue 12 laterally relative to the bone 16. After appropriate positioning of the soft tissue 12, the medial bone anchor 20 may then be inserted into the bone 16. The lateral bone anchor 22 may then be inserted into the bone 16. The suture 12 may then be passed over the soft tissue 12 and attached to the lateral bone anchor 22. In some embodiments, a lateral bone anchor 22 is provided to which suture 12 can be attached without tying any knots or without passing the suture 12 through any aperture in the lateral bone anchor 22.

In some embodiments, multiple anchors and multiple suture lengths may be used to provide a wider area of pressure of the soft tissue against bone. For example, as depicted in FIG. 3A, three anchors are used with two lengths of suture 26 and 28. Alternatively, a mesh structure 29 may be stretched between the three anchors. In another example, as depicted in FIG. 3B, four anchors are used with two lengths of suture. In still another example, as depicted in FIG. 3C, four anchors are used with four lengths of suture. In some embodiments, the individual suture lengths may be part of a larger continuous suture. For example, in FIG. 3A, the suture lengths 26 and 28 may be part of a larger length of suture such that the lengths 26 and 28 are joined at medial bone anchor 20. Those of skill in the art will appreciate that there are any number of anchor and suture geometries that can be used.

In some embodiments, the medial bone anchors 20 are designed so that they can be easily pierced through the soft tissue 12 and bone 16. In some embodiments, the lateral bone anchors 22 are designed so that they can easily capture suture material after insertion of the bone anchors 22. Together, these design features provide a suturing system and method that provides an increased footprint of suture pressure against the soft tissue 12 and ease of implementation for a surgeon.

For example, in some embodiments, the entire procedure may be done arthroscopically, with the surgeon needing only to insert the medial bone anchor 20 with suture optionally pre-attached through a first port, insert the lateral anchor 22 through a second port, pass the suture over the soft tissue 12 by capturing it from within the second port, and securing the suture to the lateral anchor 22. Accordingly, described below are certain embodiments of anchors adapted to capture suture material and anchors adapted to easily pierce through soft tissue and bone.

#### Suture Capturing Anchor

One embodiment is a bone anchor that allows easy capturing and securing of a suture after the bone anchor is inserted into the bone. In one embodiment, the bone anchor includes a suture securing mechanism positioned on the proximal end of the bone anchor (i.e., the end nearest the surface of the bone and the surgeon). In one embodiment, the suture securing mechanism allows a suture to be moved laterally into the

US 8,109,969 B1

5

mechanism. By "laterally," it is meant that the suture can be moved into the mechanism by moving the suture in a direction that is generally perpendicular to the axis of the suture. In other words, the suture can be moved into the mechanism without threading an end of the suture into the mechanism. In one embodiment, the suture can be fixedly secured within the mechanism without tying any knots. By "fixedly secured," it is meant that the suture within the securing mechanism cannot be easily moved relative to the bone anchor.

One embodiment is a bone anchor that allows easy attachment of suture material by clamping the suture material between two surfaces on the bone anchor. The bone anchor may be configured such that the bone anchor is inserted into the bone without the suture material attached. The two surfaces of the suture securing mechanism may be spaced apart so as to form a gap between the surfaces. The suture material may be passed between the two surfaces and tensioned as desired followed by clamping of the two surfaces together, thereby clamping the suture material there between.

In one embodiment, the bone anchor consists of two parts: an anchor base and an anchor top. The anchor base may be designed to be inserted into a hole in the bone with a proximal surface facing up. The anchor top may be coupled to the anchor base via a distal member. A proximal member on the anchor top may have a distal surface facing down toward the proximal surface on the anchor base. The coupling of the anchor top to the anchor base may be such that the anchor top can move relative to the anchor base such that it can be positioned in one configuration where there is space between the proximal surface on the anchor base and the distal surface on the proximal member of the anchor top. In another configuration, the proximal member of the anchor top may be positioned such that there is very little space, if any, between the proximal surface on the anchor base and the distal surface on the proximal member of the anchor top. Thus, in the first configuration, suture material may be easily passed between the two surfaces and tensioned as desired. In the second configuration, the suture material may be clamped between the two surfaces such that the suture is secured to the bone anchor.

One embodiment of an anchor base 100 is depicted in FIGS. 4A through 4D. FIG. 4A is a perspective view showing the side 101 and bottom 102 of the anchor base 100. The bottom 102 of the anchor base 100 may advantageously be tapered to facilitate insertion of the anchor base 100 into bone. In some embodiments, a hole is predrilled into the bone to facilitate insertion of the anchor base 100. In other embodiments, the anchor base 100 is forced directly into the bone, thereby creating the hole. The sides 101 of the anchor base 100 comprise threads 104 so that the anchor base 100 may be inserted into bone using a screwing action. In some embodiments, the anchor base 100 may be tapped to start the threads 104 into the bone followed by screwing the anchor base 100 into the bone. When the hole in the bone is pre-drilled, the hole is advantageously drilled with a diameter smaller than the diameter of threads 104 so that the threads engage the bone through the sides of the hole. It will be appreciated that means other than threads may be used to secure the anchor base 100 to bone. For example, angled protrusions may be used that provide greater resistance to removal of the anchor base 100 than to insertion. The protrusions may be static or deployable once the anchor is inserted.

The top of anchor base 100 preferably includes a structure 106 for facilitating the driving or screwing of the base 100 into the bone. In the illustrated embodiment, this comprises a hex nut structure 106 that facilitates engagement with a hex nut driver for screwing the anchor base 100 into the bone. It

6

will be appreciated that other structures known in the art for engaging tools used for screwing action may be used instead of hex nut structure 106, and that this structure can be indented into or extending out from the top of the anchor base 100, or can alternatively be formed on the sides of the anchor base 100.

With reference to FIG. 4B, which is a perspective view of the top and side of anchor base 100, the top (proximal end) comprises a hole 108 in the center for receiving the anchor top, which is described below. The top of anchor base 100 also contains a suture gripping structure such as a circular groove 110 that may be concentric with hole 108. Because of groove 110, the proximal surface of anchor base 100 is not flat and comprises top surfaces 112 and 114, bottom surface 116, and side surfaces 118 and 120. In some embodiments, some or all of these surfaces may be textured such as with a scallop shape or grooves so as to inhibit movement of suture material pressed against the surfaces. Although a grooved surface is illustrated, it will be appreciated that other shapes for the proximal surface of anchor base 100 are also contemplated, including multiple concentric grooves, a series of protruding ridges, a "vee" shaped channel, or any other suitable structure that permits a suture to be securely locked against the top or proximal end of the anchor base 100.

Hole 108 in anchor base 100 is an opening into a central ("axial") bore into the anchor base 100. The sides of the central bore preferably include structures for gripping something inserted into the central bore, such as ratchet structures 122. FIG. 4C show a central ratchet bushing 126 that fits within the central bore and contains the ratchet structures 122. In the embodiment of FIG. 4C, the ratchet structures 122 are constructed by cutting U shaped cuts into bushing 126. The U shaped cuts then define tabs that make up the ratchet structures 122. It will be appreciated that other shapes and methods for making ratchet structures may be used. The purpose of ratchet bushing 126 is to receive the anchor top and secure it to the anchor base 100. It will be appreciated that other methods of securing the anchor top to the anchor base 100 may be used, such as a frictional fit or threading. Furthermore, the anchor top may be coupled to the anchor base 100 using means other than hole 108 and bushing 126. For example, the anchor top may be coupled via structures at the perimeter rather than the center or by a hinge.

FIG. 4D depicts a cross section through the center of anchor base 100. This view illustrates central bore 130 and groove 110. The proximal surfaces 112, 114, 116, 118, and 120 are also apparent. Central bore 130 preferably does not extend all the way through the anchor base 100. Instead, a smaller bore 132 is present at the distal end 102 of the anchor base 100. Smaller bore 132 is used to receive a wire connected to an anchor inserter. It will be appreciated that other structures than bore 132 may be used for attaching the wire and that other means than a wire may be used to secure the anchor to the anchor inserter.

FIGS. 5A through 5C illustrate one embodiment of an anchor top 200. FIG. 5A provides a perspective view of the side and top of the anchor top 200 and FIG. 5B provides a perspective view of the side and bottom of the anchor top 200. Anchor top 200 has two members, a distal member 202 and a proximal member 204. The distal member 202 comprises an elongated shaft, the longitudinal direction of which shall be considered to run along the axis of the distal member 202. A series of grooves or other mating or locking surfaces or structures 206 exist along a portion of the outside surface of the shaft. The distal member 202 is designed to be inserted into the central bore 130 of the anchor base 100. The ratchet structures 122 in the anchor base 100 engage grooves 206 to



US 8,109,969 B1

7

couple the anchor top 200 to the anchor base 100. The ratchet structures 122 are oriented such that the distal member 202 can be easily moved in the distal direction in central bore 130 with the ratchet structures 122 snapping into the grooves 206 as the distal member 202 is moved downward. However, when the ratchet structures 122 are snapped into grooves 206, proximal movement of distal member 202 is inhibited. Thus, the anchor top 200 may be ratcheted down into anchor base 100. Because the ratchet structures 122 exist along substantially the entire surface of the central bore 130 (see FIG. 4C), the anchor top 200 may be coupled to the anchor base 100 in several positions. In other words, in one embodiment the anchor top 200 need not be ratcheted into the anchor base 100 as far as it will go for it to be secured to the anchor base 100.

The proximal member 204 of anchor top 200 is generally cylindrical in shape with a diameter larger than distal member 202. A hole 208 may advantageously be provided in the center of proximal member 204. With reference to FIG. 5B, the bottom of distal member 202 also contains a hole 210. Holes 208 and 210 open into a central bore through the anchor top 200. This central bore allows the wire referred to above to extend through the anchor top 200 to be secured to bore 132 in the anchor bottom 100, thus allowing the anchor bottom 100 to be attached to an anchor inserter while still allowing anchor top 200 to be ratcheted into anchor bottom 100. FIG. 5B also illustrates that proximal member 204 contains a groove 212 in its distal surface. Thus, the distal surface of proximal member 204 is not flat and comprises distally facing surfaces 214 and 216 and side facing surfaces 218 and 220. In some embodiments, some or all of these surfaces may be textured such as with a scallop shape or grooves so as to inhibit movement of suture material pressed against the surfaces. In some embodiments, texturing in the distal surfaces of proximal member 204 match texturing in the proximal surfaces of anchor base 100. It will be appreciated that the illustrated embodiments represent only one possibility; thus, other shapes for the distal surface of proximal member 204 may also be used. FIG. 5C depicts a cross section through the center of anchor top 200. In this figure, the central bore 226 is depicted as are surfaces 214, 216, 218, and 220 and grooves 206.

FIGS. 6A and 6B depict cross sections showing how the anchor top 200 may be coupled to anchor base 100 to form the complete anchor 300. In FIG. 6A, the anchor top 200 is coupled to anchor base 100 with the proximal member 204 separated from the anchor base 100. The anchor top 200 is secured to anchor base 100 by distal member 202 extending into central bore 130 of the anchor base 100. The distal member 202 is secured by ratchet structures (not shown) engaging grooves 206 in distal member 202. Central bore 226 in anchor top 200 and central bore 130 in anchor base 100 allow a wire to extend into the top of the anchor 300 and be secured to bore 132. Alternatively, the wire may be secured at other locations within central bore 130. Thus the wire, which can be coupled to an anchor inserter, can hold the entire anchor assembly 300 and still allow anchor top 200 to move relative to anchor base 100 and the wire.

FIG. 6B depicts the anchor assembly 300 with the distal member 202 of anchor top 200 ratcheted all the way into central bore 130 in anchor base 100. In this configuration, it can be seen that proximal surfaces 112, 114, 116, 118, and 120 of the anchor base 100 and distal surfaces 214, 216, 218, and 220 of the proximal member 204 of anchor top 200 form passageways 302 and 304. The size of passageways 302 and 304 are advantageously such that when a suture passes through them, it will be compressed so that it is securely attached to the anchor 300.

8

Another embodiment of the present invention is an inserter designed to insert and manipulate an anchor such as described in FIGS. 1-3. One such inserter 400 is depicted in FIGS. 7A and 7B. Inserter 400 comprises a handle 402 and an outer tube 404. As depicted in FIG. 7A, the handle 402 comprises a cover 403. FIG. 7B depicts the inserter 400 with cover 403 removed. Not depicted in FIGS. 7A and 7B are an inner tube disposed inside outer tube 404 and a wire disposed within the inner tube. As will be described in more detail below, the inner and outer tubes may be used to manipulate an anchor 300 such as that described in FIGS. 4-6. The wire may be used to couple the inserter 400 to the anchor 300 as described above. Inserter 400 also comprises an outer tube manipulator 406 and a wire manipulator 408. Outer tube manipulator 406 comprises release button 410. Outer tube manipulator 406 is securely attached to outer tube 404. Outer tube manipulator 406 may move longitudinally relative to handle 402 and the inner tube when release button 410 is pressed. Thus, when outer tube manipulator 406 is moved, outer tube 404 also moves.

Wire manipulator 408 comprises wire grabber 410 to which the wire is attached. The wire extends from wire grabber 410, through handle 402, and then through the inner tube. In one embodiment, wire manipulator 408 also comprises a release button 412. When release button 412 is pressed, the wire manipulator 408 may be pressed into the handle 402 to contact and thus provide additional tension on the wire. When in use, the additional tension causes the anchor base 100 to move relative to inserter 400. When enough tension is provided to the wire by wire manipulator 408, the wire may break free from the anchor 300 at its attachment point in bore 132 or at some other predetermined location along the wire. It will be appreciated that any suitable breakable attachment means may be used for securing the wire to the anchor 300. For example, the wire may be frictionally secured into bore 132 or it may be welded to the anchor base 100 using a weld that is weaker than the wire itself or a portion of the wire where breaking is desired may be weakened. In one embodiment, the wire is notched so as to create a weaker region in the wire that will break upon application of suitable force.

The tip 414 of outer tube 404 is depicted in more detail along with inner tube 420, wire 422, and anchor 300 in FIG. 8. The end of outer tube 404 may comprise a hex nut driver structure 424 for receiving the hex nut structure 106 of anchor base 100. Of course, any other suitable engagement structure can be provided on the inserter 400 and the anchor base 100 in order to facilitate placement of the anchor base 100. Wire 422 extends out of inner tube 420 and into the central bore in the anchor top 200 to attach to anchor base 100 as described above. In some advantageous embodiments, the wire length and tension is adjusted such that the proximal member 204 of anchor top 200 butts against the end 426 of inner tube 420.

FIGS. 9A through 9E depict how inserter 400 and anchor 300 may be used to insert the anchor 300 into bone and attach a suture to it. FIG. 9A depicts the configuration for inserting the anchor 300 into bone. Outer tube 404 and outer tube manipulator 406 (see FIGS. 7A and 7B) are positioned relative to inner tube 420 and handle 402 (see FIGS. 7 and 8) so that the outer tube 404 engages hex nut structure 106 in the anchor base 100. It is advantageous in this configuration for the anchor top 200 to be in a position relative to the anchor base 100 such as depicted in FIG. 6A. In the configuration of FIG. 9A, a surgeon may then screw the anchor base 100 into bone by twisting handle 402 of inserter 400 (see FIGS. 7A and 7B).

After the anchor base 100 is inserted into the bone, the outer tube 404 may be slid backward relative to the inner tube 420 and handle 402 to expose the anchor top 200 such as in

US 8,109,969 B1

9

FIG. 9B. One or more lengths of suture 600 may then be placed in the space between the distal surface 602 of the proximal member 204 of anchor top 200 and the proximal surface 604 of the anchor base 100 by moving the suture laterally into the space as depicted in FIG. 9C. The suture 600 may be manually tensioned as desired. In some embodiments, tensioning of the suture 600 is aided by pulling the suture 600 against the distal member 202 of the anchor top 200.

After appropriate tensioning of suture 600, wire manipulator 408 may be pressed to tension the wire, causing the handle 402 of the inserter 400 and the inner tube 420 to be pulled down towards the anchor base 100 so that inner tube 420 ratchets the anchor top 200 down into the anchor bottom 100 as depicted in FIG. 9D. As the anchor top 200 is pushed axially down, suture 600 will be clamped between the distal surface 602 of the proximal member 204 of anchor top 200 and the proximal surface 604 of the anchor base 100 (see also FIG. 9C). The clamping will force the suture to be compressed within the passageways 302 and 304 depicted in FIG. 6B and thus be secured to anchor 300. The fit between the anchor top 200 and the anchor base 100 in the clamping region is such that the suture 600 is firmly gripped, but is not cut, when it is clamped in place. Appropriate edges that may contact the suture are preferably beveled or rounded to avoid damage to the suture. After anchor top 200 is ratcheted sufficiently into anchor base 100, wire manipulator 408 (see FIGS. 7A and 7B) in inserter 400 may be compressed further to further tension wire 422 (see FIG. 8) such that wire 422 breaks free from its attachment to anchor base 100, thus leaving the anchor 300 free from inserter 400 with suture 600 securely attached as depicted in FIG. 9E.

Although a particular inserter device for inserting and manipulating anchor 300 has been described, it should be understood that other inserter designs may be used for manipulating the parts of anchor 300 described above to insert the anchor into bone and secure suture material to the anchor. For example, it may be possible to use separate tools for inserting the anchor and securing the suture material. In addition, in alternative embodiments, the anchor base 100 may be connected to the anchor top 200 throughout the procedure, or the anchor base may be separately inserted into the bone, and the anchor top can be attached thereafter by axially sliding the distal end of the anchor top 200 into the hole 108 in the anchor base 100.

It will be appreciated by those of skill in the art that the anchor 300 and inserter 400 provide a system for easy attachment of a suture to bone. The anchor 300 may be inserted into bone with minimal disruption of surrounding tissue. Only an access route having the diameter of the outer tube 404 and the anchor base 100 is required. Furthermore, the suture can be securely attached to the anchor 300 and tensioned as desired without having to insert additional instrumentation into the site or without performing any cumbersome attachment maneuvers such as knot tying. It should also be appreciated that the general principle illustrated by this system of inserting an anchor into bone without having suture material pre-attached and then attaching suture to the anchor without tying any knots may be implemented using any appropriate system other than the specific embodiments depicted in FIGS. 4-9. Tissue and Bone Piercing Anchor

One embodiment is a bone anchor adapted for piercing through the soft tissue and into underlying bone. In one embodiment, the suture material may be pre-attached to the piercing bone anchor so that after implantation, a suture passes from the bone anchor through to the top of the soft tissue for easy passing over the soft tissue. In one embodiment, the piercing bone anchor has two configurations, a first

10

configuration having a small diameter for easy piercing through soft tissue and bone and a second deployed configuration where structures such as protrusions are deployed to prevent the bone anchor from being easily removed from the bone.

In one embodiment, the anchor includes a substantially hollow cylinder having a portion of its walls cut in such a manner so as to allow the cylinder to deform under axial stress and form lateral protrusions. The lateral protrusions may thus prevent the anchor from being easily removed from the bone after deployment. In one embodiment, the anchor comprises a pointed tip coupled to the hollow cylinder for piercing the soft tissue and bone. In one embodiment, suture is pre-attached to the pointed tip inside of the hollow cylinder. In other embodiments, suture is pre-attached at other locations on the piercing anchor, such as at the proximal end of the hollow cylinder.

One embodiment of a deployable piercing anchor is depicted in FIGS. 10A and 10B. In FIG. 10A, the anchor is depicted in a pre-deployed state. The anchor includes a substantially hollow cylinder 650 with a plurality of cuts 652 in the side of the cylinder 650. The cylinder 650 is open on one end 654. On the other end, a pointed tip 656 is disposed, allowing the anchor to pierce through soft tissue and bone. In FIG. 10B, the anchor is depicted in a deployed state. Stress is applied in an axial direction such that the cylinder 650 collapses along cuts 652 so as to form two lateral wings 660. The lateral wings 660 prevent the anchor from being removed from the bone. Hinges 662 connect one end of each wing to either the top or the bottom parts of anchor body. These hinges deform and fold, in the plane tangent to the anchor body at that point when the anchor is deployed. A strip of material 664 connects the top and bottom wing on each side of the anchor body, and serves as a hinge between the two as well as aiding in alignment of the wings during deformation. The tips of the wings adjacent to the connecting strip 664 utilize rolling edges 666, which ensure uniform alignment and smooth transition during deformation. Those of skill in the art will appreciate that any number of geometries of cuts in the cylinder 650 may be utilized to create a deformable structure that will produce lateral protrusions upon exposure to stress.

In some embodiments, structures may be positioned within the cylinder 650 for attaching sutures and engaging with an anchor inserter. In one embodiment, such structures are coupled to the anchor tip 656 within the cylinder 650. FIG. 11 depicts one such embodiment. Attached to the tip 656 is a structure 670 through which there is an aperture 672. The structure 670 may be adapted to engage the inner surface of cylinder 650 for attaching the tip 656 to the cylinder 650. The attachment mechanism may be by forced fit, frictional fit, threads, welding, adhesive, or any other suitable means. Suture material may be threaded through the aperture 672 in order to attach the suture to the anchor. The suture material may be secured to the tip 656 by tying the suture around structure 670, tying a knot in the end of the suture that prevents it from being pulled through the aperture 672, clamping the suture between the structure 670 and the inside of the cylinder 650, adhering the suture to structure 670 by welding or adhesive, or any other suitable means. In one embodiment, the suture material is attached to the anchor at tip 656 prior to use of the anchor.

An anchor inserter attachment structure 674 may also be coupled to the tip 656. This structure 674 may couple to an anchor inserter through a wire or any other suitable means. The attachment between the anchor inserter and the anchor at this point may be used to apply axial stress to the anchor for

US 8,109,969 B1

11

deploying the anchor as described above. The attachment at this point may also serve to keep the anchor attached to the inserter prior to deployment.

One embodiment of an anchor inserter suitable for use with the above-described anchor is depicted in FIG. 12. The anchor inserter comprises a grasping handle 700 to which is attached an outer sleeve 702 which is fixed relative to the handle 700. The piercing anchor 704 is disposed at the end of the sleeve 702. A deployment lever 706 may be pressed by a user to deploy and detach the anchor 704 as described below. A safety switch 708 may be provided to prevent the anchor 704 from being deployed prematurely. A spool 710 may be provided at the proximal end of the handle 700 for holding excess suture. A lid 712 may be provided for gaining access to the inner components of the inserter.

FIG. 13 depicts the anchor 704 coupled to the inserter. As described above, the anchor 704 comprises a hollow cylinder 650 with cuts in the sides and a pointed tip 656. Furthermore, as depicted in FIG. 11, a suture receiving aperture 672 and an inserter attachment structure 674 are attached to the pointed tip 656 within the cylinder 650. The outer sleeve 702 of the inserter may fit over the open end 654 of the cylinder 650 or be flush with the open end 654. The outer sleeve 702 may thus hold the top part of the anchor 704 steady during insertion. In an alternative embodiment, the outer sleeve 702 may fit over the length of the cylinder 650 to prevent the cylinder 650 from deforming while it is being inserted into bone. In this alternative embodiment, the outer sleeve 702 may be retracted prior to deployment of the anchor. An inner tube 720 may be positioned within the outer sleeve 702 and the hollow cylinder 650 and contact the top surface of the anchor tip 656 (see FIG. 11). The inner tube 720 provides structural reinforcement of the anchor 704 and pushes against the tip of the anchor 704 while it is being driven into bone or tissue. The inner tube 720 may be fixed relative to the handle 712 and outer sleeve 702 during insertion, however, during deployment of the anchor 704, the inner tube 720 may be released by switching safety switch 708 so that the inner tube 720 can move axially relative to the outer sleeve 702 while the anchor cylinder 650 collapses. A wire may be positioned inside of the inner tube 720 running from within the handle 712 through the inner tube 720 to the anchor 704 and attached to the anchor inserter attachment structure 674. During deployment, the lever 704 may be pressed to pull the wire axially towards the handle 700. The axially movement of the wire forces the anchor 704 to press against outer sleeve 702 and stresses the cylinder 650, causing it to deform and deploy. During collapse of the cylinder 650, the inner tube 720 will also move in an axial direction toward the handle 700. Upon further stress on the wire, the wire may break free from the anchor inserter attachment structure 674, releasing the inserter from the anchor 704. Suture material may run from the inside of handle 700 through the inner tube 720 to attach to the anchor 704 through aperture 672 (see FIG. 11). Upon detachment of the anchor inserter from the anchor 704, the inserter may be withdrawn, leaving the inserted and deployed anchor with suture coming out of the open end 654 of the cylinder 650. The suture will still be coupled to the inserter through the inner tube 720, handle 700, and around spool 710. Those of skill in the art will appreciate other inserters and mechanisms that may be used to insert and deploy the piercing anchors described herein. For example, rather than axially stressing the anchor 704 by pulling the tip 656 in an proximal direction, the cylinder 650 may be pushed in a distal direction to deform the cylinder 650.

FIG. 14 is a cut-away view of the handle 700, showing the inner workings of the anchor inserter. The suture material attached to a piercing anchor at the tip of the inserter may pass

12

through the central bore of the inner tube 720 and through a bore 750 in the handle 700. The suture material may then pass through a hole 752 in the end of the handle 700 and be wrapped around the spool 710, which may be integral with the handle 700. The wire attached to the anchor inserter attachment structure 674 in the anchor may also pass through the central bore of the inner tube 720 and may then proceed around a pulley 754 and attach securely to the handle 700 at point 756. The pulley 754 may be attached to the lever 706. When the lever 706 is pressed down, the pulley 754 will move toward the back end of the handle 700, causing the wire attached to the anchor to retract. Because of the use of pulley 754, the wire will retract twice the distance as the pulley 754 moves.

The safety switch 708 may be used to prevent the lever 706 from being pressed and prevent the inner tube 720 from moving unless the safety switch 708 is in the correct position. The safety mechanism operates via a drum 760 disposed within the handle 700 to which the safety switch 708 is attached. Moving the safety switch 708 rotates the drum 760 within the handle 700. FIG. 15 shows the drum 760 and safety switch 708 mechanism in more detail. The inner tube 720 passes through a central bore in the drum 760. On the other side of the drum 760, the inner tube 720 is attached to a stopper 762. The stopper 762 has a through-hole 764 to permit passage of the deployment wire and suture. The stopper 762 may be positioned within a cavity 766 in the end of the drum 760. A second similarly shaped cavity may be disposed within the handle 700. The stopper 762 and attached inner tube 720 may only be allowed to move axially relative to the handle 700 when the safety switch 708 and drum 760 is rotated so that the cavity 766 in the drum 760 is aligned with the matching cavity in the handle 700. When the cavities are aligned, the stopper 762 is allowed to move from the cavity 766 to the cavity in the handle 700, thus allowing the inner tube 720 to move axially and the anchor to be deployed.

Additionally, the drum 760 comprises a groove 768. A spring-loaded sliding pin 770 (see FIG. 14) may be coupled to the lever 706. The lever 706 can only be moved when the drum 760 and switch 708 are rotated so that groove 768 is aligned with the pin 770. Thus, both the stopper 764 and the pin 770 prevent the anchor from being deployed unless the switch 708 is in the correct position.

Those of skill in the art will appreciate other mechanisms that could be used for deploying a deployable anchor and providing safety mechanisms to prevent premature deployment.

#### Example Using a Piercing Anchor and a Suture Capturing Anchor

The above-described anchors may be used in a surgical procedure for attaching soft tissue to bone. One example of such a procedure is depicted in FIGS. 16A through 16F. In FIG. 16A, the piercing anchor 800 attached to an anchor inserter 802 as described above is pierced through soft tissue 804 that has become detached from underlying bone 806. In FIG. 16B, the anchor inserter 802 is moved laterally relative to the bone 806 so as to stretch the soft tissue 804 laterally relative to the bone 806. Once the soft tissue 804 has been stretched to the desired position, the anchor 800 is inserted into the bone 806 and the anchor 800 is deployed as described above and the inserter 802 is detached from the anchor 800, leaving a suture 808 attached to the anchor 800 and extending through the soft tissue 804. The anchor 800 may be inserted into bone 806 by tapping on the inserter 802 with a hammer or by any other suitable means of applying axial force. FIG. 16C depicts the deployed anchor 800 with attached suture 808. The suture 808 will extend into the inserter 802.



US 8,109,969 B1

13

Next, as depicted in FIG. 16D, a suture capturing anchor 810 is inserted into the bone 806 using the inserter 812 as described above. In FIG. 16E, the inserter 812 is then retracted to expose the suture capturing mechanism. The suture 808 is then passed over the soft tissue 804 and laterally moved into the suture capturing mechanism and tensioned. Finally, as depicted in FIG. 16F, the suture capturing mechanism is deployed to capture the suture 808, the anchor inserter 812 is detached from the anchor 810, and the suture 808 is cut to detach it from the suture inserter 802. The result is a length of suture 808 between the bone anchors 808 and 810 that presses the soft tissue 804 against the bone 806. Multiple anchors and sutures may be used to produce geometries such as depicted in FIGS. 2 and 3 and variations thereof.

It will be appreciated that there are numerous stitches, suture threading patterns, and anchor patterns that may be used to secure soft tissue to bone by the methods and devices described herein. These variations as well as variations in the design of the above described anchor devices and inserter devices are within the scope of the present disclosure.

#### Methods of Attaching Soft Tissue to Bone

Various embodiments include methods for attaching soft tissue to bone. In some embodiments, the methods include using the bone anchors described above. In one embodiment, a bone anchor is inserted into the bone and then a length of suture is passed over the soft tissue and secured to the anchor after inserting the anchor without tying any knots or without passing the suture through an aperture in the anchor. In some embodiments, the suture is secured to the anchor by laterally moving it into a securing mechanism. In one embodiment, securing the suture to the anchor includes clamping the suture between at least two surfaces on the anchor. In one embodiment, the anchor is not inserted further into the bone after securing the suture to it.

In another embodiment, a first anchor with a suture pre-attached is inserted through the soft tissue and into the bone. The suture may then be passed over the soft tissue and fixedly secured to a second bone anchor. In one embodiment, the first anchor is inserted by directly piercing the soft tissue and the bone. In one embodiment, lateral protrusion may be deployed on the first anchor to prevent the first anchor from being removed. In one embodiment, the suture may be coupled to the second bone anchor prior to insertion and then fixedly secured after insertion. In this context, "coupled" means that the suture is attached to the bone anchor but not fixedly secured, such that the suture can move to some extent relative to the bone anchor. In an alternative embodiment, the suture is not coupled to the second bone anchor during its insertion.

In another embodiment, a first portion of suture is inserted into the proximal surface of the soft tissue. A second portion of the suture (e.g., the portion proximal to the inserted portion) is then passed over the proximal surface of the soft tissue and fixedly secured to a bone anchor. In one embodiment, the procedure may be performed without passing the first portion of the suture back out of the proximal surface of the soft tissue. In one embodiment, this result is accomplished by the first portion of the suture being attached to an anchor that is inserted through the soft tissue and into bone.

One embodiment includes inserting a first anchor with a pre-coupled suture through soft tissue and into bone. The suture may then be passed over the soft tissue and fixedly secured to a second anchor. In one embodiment, the pre-coupled suture is fixedly secured to the first anchor prior to insertion. In an alternative embodiment, the pre-coupled suture can move relative to the first anchor prior to insertion and is fixedly secured after insertion.

14

In another embodiment, multiple lengths of suture are attached to multiple anchors. In one embodiment at least three anchors are inserted into bone. A first length of suture may be secured between a first and second anchor and a second length of suture may be secured between the first and a third anchor. In one embodiment, the first anchor is positioned beneath the soft tissue and the second and third anchors are positioned laterally to the soft tissue. In an alternative embodiment, the first anchor is positioned laterally to the soft tissue and the second and third anchors are positioned beneath the soft tissue. In some embodiments, the lengths of suture are fixedly secured to the anchor(s) positioned beneath the soft tissue prior to insertion of those anchor(s). In one embodiment, the different lengths of suture may be tensioned separately.

In various embodiments, prior to fixedly securing suture to a bone anchor, it can be tensioned. In one embodiment, tensioning is accomplished by manually pulling on the suture such as by a surgeon grasping the suture using an appropriate instrument and then pulling. In one embodiment, the suture may be pressed against the bone anchor to provide leverage for pulling. For example, the suture may be wrapped partly around a proximal portion of the anchor prior to pulling.

Although the invention has been described with reference to embodiments and examples, it should be understood that numerous and various modifications can be made without departing from the spirit of the invention. Accordingly, the invention is limited only by the following claims.

#### What is claimed is:

1. A method of attaching soft tissue to bone, comprising: inserting a first anchor into bone, wherein after insertion, the first anchor is positioned underneath the soft tissue; passing a first length of suture from said first anchor over the soft tissue; inserting at least a portion of a second anchor into bone at a position beyond an edge of the soft tissue; after inserting said at least a portion of the second anchor, tensioning the first length of suture to compress an area of tissue to bone between the edge of the soft tissue and the first anchor; and after tensioning the first length of suture, fixedly securing the first length of suture at the second anchor position without tying any knots;
- wherein at least one of said anchors comprises an anchor tip and a hollow cylinder, wherein the anchor tip comprises an aperture through which suture material is threaded prior to insertion of the at least one anchor.
2. The method of claim 1, wherein said anchor tip comprises an engaging member adapted to engage an inner surface of said cylinder.
3. The method of claim 1, wherein said anchor tip comprises an anchor inserter attachment member.
4. The method of claim 3, wherein insertion of the at least one anchor comprising an anchor tip and a hollow cylinder comprises using an inserter that comprises a handle, an outer sleeve, and an inner member, wherein the inner member extends through the outer sleeve and the hollow cylinder and is attached to the anchor inserter attachment member.
5. The method of claim 4, wherein the inserter comprises an inner tube extending through the outer sleeve and through the hollow cylinder and contacts the anchor tip, wherein the inner member extends through the inner tube.
6. The method of claim 5, wherein the inner tube is fixed relative to the handle.
7. The method of claim 5, wherein the inner tube is movable axially relative to the outer sleeve.

## US 8,109,969 B1

## 15

8. The method of claim 5, wherein suture material runs from inside the handle of the inserter, through the inner tube, and through the aperture in the anchor tip.

9. The method of claim 8, wherein the suture material runs through a bore in the handle and passes through a hole in an end of the handle. 5

10. The method of claim 9, wherein the handle comprises a spool at a proximal end of the handle adapted to hold excess suture.

11. The method of claim 10, wherein the suture material is wrapped around the spool. 10

12. The method of claim 11, wherein the spool is integral with the handle.

13. The method of claim 4, wherein insertion of the at least one anchor comprising an anchor tip and a hollow cylinder comprises tapping on the inserter with a hammer. 15

14. The method of claim 1, comprising coupling the first length of suture to the at least one anchor comprising an anchor tip and a hollow cylinder prior to inserting the at least one anchor comprising an anchor tip and a hollow cylinder.

15. The method of claim 1, wherein the tensioning comprises manually pulling on the first length of suture. 20

16. The method of claim 1, comprising:

inserting a third anchor into bone, wherein after insertion, the third anchor is positioned underneath the soft tissue; passing a second length of suture from said third anchor over the soft tissue; 25

tensioning the second length of suture independently from the first length of suture; and

after tensioning the first and second lengths of suture, fixedly securing both the first and second lengths of suture at the second anchor position without tying any knots. 30

## 16

17. A method of attaching soft tissue to bone, comprising: inserting a first anchor into bone, wherein after insertion, the first anchor is positioned underneath the soft tissue; passing a first length of suture from said first anchor over the soft tissue;

inserting at least a portion of a second anchor into bone at a position beyond an edge of the soft tissue;

after inserting said at least a portion of the second anchor, tensioning the first length of suture to compress an area of tissue to bone between the edge of the soft tissue and the first anchor; and

after tensioning the first length of suture, fixedly securing the first length of suture at the second anchor position without tying any knots;

wherein at least one of said anchors comprises an anchor tip and a hollow cylinder, wherein the anchor tip comprises:

an aperture through which suture material is threaded prior to insertion of the at least one anchor,

an engaging member adapted to engage an inner surface of said cylinder, and

an anchor inserter attachment member, wherein insertion of the at least one anchor comprising an anchor tip and a hollow cylinder comprises using an inserter that comprises a handle, an outer sleeve, and an inner member, wherein the inner member extends through the outer sleeve and the hollow cylinder and is attached to the anchor inserter attachment member.

\* \* \* \* \*

# **EXHIBIT 4**

Docket No.: **KFX.003C1**

**Customer No. 20995**

**INFORMATION DISCLOSURE STATEMENT**

Applicant	:	Michael L. Green et al.
App. No.	:	13/245620
Filed	:	September 26, 2011
For	:	SYSTEM AND METHOD FOR ATTACHING SOFT TISSUE TO BONE
Examiner	:	Gregory A. Anderson
Art Unit	:	3773
Conf. No.	:	9919

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Enclosed is a PTO/SB/08 Equivalent listing **201 references**. References numbered 1-87, 89-98, 100-109, 114-141, 143-149, 151-157, 159-160, 162-166, 168-169, 171-182, 185-190, 194, and 200 are of record in U.S. patent application No. 12/549,105, filed August 27, 2009, which is relied upon for an earlier filing date under 35 U.S.C. § 120. Accordingly, copies of references numbered 88, 99, 110-113, 142, 150, 158, 161, and 167 are not submitted pursuant to 37 C.F.R. § 1.98(d).

This Information Disclosure Statement is being filed before the receipt of a first Office Action on the merits, and presumably no fee is required. If a first Office Action on the merits was mailed before the mailing date of this Statement, the Commissioner is authorized to charge the fee set forth in 37 C.F.R. § 1.17(p) to Deposit Account No. 11-1410.

**Application No.:** 13/245620  
**Filing Date:** September 26, 2011

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

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PTO/SB/08 Equivalent

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>	Application No.	13/245620
	Filing Date	09-26-2011
	First Named Inventor	Green, Michael L. et al
	Art Unit	3773
(Multiple sheets used when necessary)	Examiner	Gregory A. Anderson
SHEET 1 OF 8	Attorney Docket No.	KFX.003C1

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Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
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	29	5,683,419	11-04-1997	Thal	

Examiner Signature	Date Considered
<p>*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>	

T<sup>1</sup> - Place a check mark in this area when an English language Translation is attached.

PTO/SB/08 Equivalent

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Multiple sheets used when necessary)</i>	Application No.	13/245620
	Filing Date	09-26-2011
	First Named Inventor	Green, Michael L. et al
	Art Unit	3773
	Examiner	Gregory A. Anderson
SHEET 2 OF 8	Attorney Docket No.	KFX.003C1

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
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	58	6,241,749 B1	06-05-2001	Rayhanabad	

Examiner Signature	Date Considered
<b>*Examiner:</b> Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

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PTO/SB/08 Equivalent

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Multiple sheets used when necessary)</i>	Application No.	13/245620
	Filing Date	09-26-2011
	First Named Inventor	Green, Michael L. et al
	Art Unit	3773
	Examiner	Gregory A. Anderson
SHEET 3 OF 8	Attorney Docket No.	KFX.003C1

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	59	6,245,082 B1	06-12-2001	Gellman et al.	
	60	6,280,474 B1	08-28-2001	Cassidy et al.	
	61	6,293,961 B2	09-25-2001	Schwartz et al.	
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	65	6,328,758 B1	12-11-2001	Tornier et al.	
	66	6,391,030 B1	05-21-2002	Wagner et al.	
	67	6,423,065 B2	07-23-2002	Ferree	
	68	6,432,123 B1	08-13-2002	Schwartz et al.	
	69	6,464,713 B2	10-15-2002	Bonutti	
	70	6,491,714 B1	12-10-2002	Bennett	
	71	6,514,274 B1	02-04-2003	Boucher et al.	
	72	6,518,200 B2	02-11-2003	Lin	
	73	6,520,980 B1	02-18-2003	Foerster	
	74	6,524,317 B1	02-25-2003	Ritchart et al.	
	75	6,527,794 B1	03-04-2003	McDevitt et al.	
	76	6,533,795 B1	03-18-2003	Tran et al.	
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	79	6,551,330 B1	04-22-2003	Bain et al.	
	80	6,554,852 B1	04-29-2003	Oberlander	
	81	6,569,187 B1	05-27-2003	Bonutti et al.	
	82	6,575,987 B2	06-10-2003	Gellman et al.	
	83	6,582,453 B1	06-24-2003	Tran et al.	
	84	6,585,730 B1	07-01-2003	Foerster	
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Examiner Signature	Date Considered
<p>*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>	

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PTO/SB/08 Equivalent

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Multiple sheets used when necessary)</i>  SHEET 4 OF 8	Application No.	13/245620
	Filing Date	09-26-2011
	First Named Inventor	Green, Michael L. et al
	Art Unit	3773
	Examiner	Gregory A. Anderson
	Attorney Docket No.	KFX.003C1

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	88	6,641,597 B2	11-04-2003	Burkhart et al.	
	89	6,652,561 B1	11-25-2003	Tran	
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	91	6,660,023 B2	12-09-2003	McDevitt et al.	
	92	6,673,094 B1	01-06-2004	McDevitt et al.	
	93	6,712,830 B2	03-30-2004	Esplin	
	94	6,770,076 B2	08-03-2004	Foerster	
	95	6,780,198 B1	08-24-2004	Gregoire et al.	
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	100	7,041,120 B2	05-09-2006	Li et al.	
	101	7,056,333 B2	06-06-2006	Walshe	
	102	7,081,126 B2	07-25-2006	McDevitt et al.	
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	108	7,232,455 B2	06-19-2007	Pedlick et al.	
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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>	Application No.	13/245620
	Filing Date	09-26-2011
	First Named Inventor	Green, Michael L. et al
	Art Unit	3773
(Multiple sheets used when necessary)	Examiner	Gregory A. Anderson
SHEET 5 OF 8	Attorney Docket No.	KFX.003C1

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
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Examiner Signature	Date Considered
<p>*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>	

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PTO/SB/08 Equivalent

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Multiple sheets used when necessary)</i>	Application No.	13/245620
	Filing Date	09-26-2011
	First Named Inventor	Green, Michael L. et al
	Art Unit	3773
	Examiner	Gregory A. Anderson
SHEET 6 OF 8	Attorney Docket No.	KFX.003C1

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	146	2004/0225325 A1	11-11-2004	Bonutti	
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	151	2005/0027307 A1	02-03-2005	Schwartz et al.	
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	164	2006/0271060 A1	11-30-2006	Gordon	
	165	2006/0271105 A1	11-30-2006	Foerster et al.	
	166	2006/0293710 A1	12-28-2006	Foerster et al.	
	167	2007/0142835 A1	06-21-2007	Green et al.	
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FOREIGN PATENT DOCUMENTS						
Examiner Initials	Cite No.	Foreign Patent Document Country Code-Number-Kind Code Example: JP 1234567 A1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T <sup>1</sup>
	169	SU 1600713	10-23-1990	Don Med Inst.		
	170	WO 1999/052478 A1	10-21-1999	Axya Medical, Inc.		

Examiner Signature	Date Considered
<b>*Examiner:</b> Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

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PTO/SB/08 Equivalent

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>	Application No.	13/245620
	Filing Date	09-26-2011
	First Named Inventor	Green, Michael L. et al
	Art Unit	3773
(Multiple sheets used when necessary)	Examiner	Gregory A. Anderson
SHEET 7 OF 8	Attorney Docket No.	KFX.003C1

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Cite No.	Foreign Patent Document Country Code-Number-Kind Code Example: JP 1234567 A1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T <sup>1</sup>
	171	WO 2001/054586 A1	08-02-2001	Shoulderon Ltd.		
	172	WO 2001/067962 A2	09-20-2001	Rosch		
	173	WO 2002/011630 A1	02-14-2002	The Cleveland Clinic Foundation		
	174	WO 2002/021998 A1	03-31-2002	Axya Medical Inc.		
	175	WO 2003/065904 A1	08-14-2003	Opus Medical, Inc.		
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	178	WO 2005/112788 A2	12-01-2005	Arthrocare Corporation		
	179	WO 2006/060035 A2	06-08-2006	3I Medical Corporation		
	180	WO 2006/067548 A1	06-29-2006	Arthrex, Inc.		
	181	WO 2006/128092 A2	11-30-2006	Arthrocare Corporation		
	182	WO 2007/084714 A2	07-26-2007	Kim		

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>1</sup>
	183	Arthrex, Inc.'s Answer to Plaintiff KFX Medical Corp.'s complaint For Patent Infringement and Counterclaims, United States District Court, Southern District of California, September 23, 2011, Los Angeles, USA.	
	184	Complaint for Patent Infringement, dated August 1, 2011, KFX Medical Corporation v. Arthrex, Inc., (S.D.C.A.).	
	185	International Preliminary Report on Patentability dated January 25, 2007 for International Application No. PCT/US2005/019454.	
	186	International Search Report and Written Opinion of the International Searching Authority, dated September 6, 2006, for International Application No. PCT/US2005/019454.	
	187	LO et al., "Double-Row Arthroscopic Rotator Cuff Repair: Re-Establishing the Footprint of the Rotator Cuff, Arthroscopy: The Journal of Arthroscopic and Related Surgery, November, 2003, pgs. 1035-1042, Vol. 19, No. 9.	
	188	MAZZOCCA et al., Arthroscopic Single-Row Versus Double-Row Suture Anchor Rotator Cuff Repair," The American Journal of Sports Medicine, 2005, 33:1861.	
	189	MAZZOCCA et al., Arthroscopic Single versus Double Row Suture Anchor Rotator Cuff Repair, abstract of presentation made on June 25, 2004 at 2004 Annual Meeting of the American Orthopaedic Society for Sports Medicine in Quebec, Canada, publication date unknown.	
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Examiner Signature	Date Considered
<p>*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>	

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Multiple sheets used when necessary)</i>	Application No.	13/245620
	Filing Date	09-26-2011
	First Named Inventor	Green, Michael L. et al
	Art Unit	3773
	Examiner	Gregory A. Anderson
SHEET 8 OF 8	Attorney Docket No.	KFX.003C1

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>1</sup>
	191	PAULOS, M.D., Graftjacket Regenerative Tissue Matrix Rotator Cuff, date unknown, Wright Medical Technology, Inc.; Wright Cremascoli Ortho SA.	
	192	PCT International Preliminary Report on Patentability, dated May 22, 2009, for International Application No. PCT/US2007/083662.	
	193	PCT International Search Report and Written Opinion, dated August 8, 2008, for International Application No. PCT/US2007/083662.	
	194	PCT Invitation to Pay Additional Fees, dated May 13, 2008, for International Application No. PCT/US2007/083662.	
	195	ROBBE, M.D. et al., Knotless Suture-based Anchors, Operative Techniques in Sports Medicine, 2004, pgs. 221-224, Elsevier Inc.	
	196	SELDES, M.D., et al., Tissue Mend Arthroscopic Insertion of a Biologic Rotator Cuff Tissue Augment After Rotator Cuff Repair, Stryker, date unknown, pgs. 1-7.	
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	198	TissueMend Advanced Soft Tissue Repair Matrix, Stryker, date unknown.	
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	200	WALTRIP, "Rotator Cuff Repair A Biomechanical Comparison of Three Techniques", The American Journal of Sports Medicine, 2003, pgs. 493-497, No. 4.	
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# **EXHIBIT 5**

Docket No.: **KFX.003C2**

Customer No. 20995

**INFORMATION DISCLOSURE STATEMENT**

Applicant	:	Michael L. Green et al.
App. No.	:	13/245622
Filed	:	September 26, 2011
For	:	SYSTEM AND METHOD FOR ATTACHING SOFT TISSUE TO BONE
Examiner	:	Gregory A. Anderson
Art Unit	:	3773
Conf. No.	:	8012

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Enclosed is a PTO/SB/08 Equivalent listing **201 references**. References numbered 1-87, 89-98, 100-109, 114-141, 143-149, 151-157, 159-160, 162-166, 168-169, 171-182, 185-190, 194, and 200 are of record in U.S. patent application No. 12/549,105, filed August 27, 2009, which is relied upon for an earlier filing date under 35 U.S.C. § 120. Accordingly, copies of references numbered 88, 99, 110-113, 142, 150, 158, 161, and 167 are not submitted pursuant to 37 C.F.R. § 1.98(d).

This Information Disclosure Statement is being filed before the receipt of a first Office Action on the merits, and presumably no fee is required. If a first Office Action on the merits was mailed before the mailing date of this Statement, the Commissioner is authorized to charge the fee set forth in 37 C.F.R. § 1.17(p) to Deposit Account No. 11-1410.



**Application No.:** 13/245622  
**Filing Date:** September 26, 2011

Respectfully submitted,  
KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: December 1, 2011

By: Ryan Melnick  
Ryan E. Melnick  
Registration No. 58,621  
Attorney of Record  
Customer No. 20995  
(858) 707-4000

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PTO/SB/08 Equivalent

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>	Application No.	13/245622
	Filing Date	09-26-2011
	First Named Inventor	Green, Michael L. et al
	Art Unit	3773
(Multiple sheets used when necessary)	Examiner	Gregory A. Anderson
SHEET 1 OF 8	Attorney Docket No.	KFX.003C2

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	1	3,623,192	11-30-1971	Button	
	2	4,210,148	07-01-1980	Stivala	
	3	4,532,926	08-06-1985	O'Holla	
	4	4,796,612	01-10-1989	Reese	
	5	4,898,156	02-06-1990	Gattorna et al.	
	6	5,013,316	05-07-1991	Goble et al.	
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	8	5,219,359	06-15-1993	McQuilkin et al.	
	9	5,224,946	07-06-1993	Hayhurst et al.	
	10	5,269,784	12-14-1993	Mast	
	11	5,336,240	08-09-1994	Metzler et al.	
	12	5,372,604	12-13-1994	Trott	
	13	5,417,712	05-23-1995	Whittaker et al.	
	14	5,423,858	06-13-1995	Bolanos et al.	
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	16	5,472,452	12-05-1995	Trott	
	17	5,478,353	12-26-1995	Yoon	
	18	5,500,001	03-19-1996	Trott	
	19	5,527,341	06-18-1996	Gogolewski et al.	
	20	5,527,343	06-18-1996	Bonutti	
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	26	5,584,835	12-17-1996	Greenfield	
	27	5,591,207	01-07-1997	Coleman	
	28	5,634,926	06-03-1997	Jobe	
	29	5,683,419	11-04-1997	Thal	

Examiner Signature	Date Considered
<p>*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>	

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	Filing Date	09-26-2011
	First Named Inventor	Green, Michael L. et al
	Art Unit	3773
	Examiner	Gregory A. Anderson
SHEET 2 OF 8	Attorney Docket No.	KFX.003C2

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	30	5,690,676	11-25-1997	DiPoto et al.	
	31	5,697,950	12-16-1997	Fucci et al.	
	32	5,720,765	02-24-1998	Thal	
	33	5,725,557	03-10-1998	Gattorna	
	34	5,769,894	06-23-1998	Ferragamo	
	35	5,800,436	09-01-1998	Lerch	
	36	5,814,072	09-29-1998	Bonutti	
	37	5,891,168	04-06-1999	Thal	
	38	5,948,001	09-07-1999	Larsen	
	39	5,948,002	09-07-1999	Bonutti	
	40	5,951,590	09-14-1999	Goldfarb	
	41	5,964,769	10-12-1999	Wagner et al.	
	42	6,010,525	01-04-2000	Bonutti et al.	
	43	6,013,077	01-11-2000	Harwin	
	44	6,013,083	01-11-2000	Bennett	
	45	6,027,523	02-22-2000	Schmieding	
	46	6,045,573	04-04-2000	Wenstrom, Jr. et al.	
	47	6,056,751	05-02-2000	Fenton, Jr.	
	48	6,063,106	05-16-2000	Gibson	
	49	6,093,201	07-25-2000	Cooper et al.	
	50	6,093,301	07-25-2000	Van Atta	
	51	6,099,547	08-08-2000	Gellman et al.	
	52	6,110,207	08-29-2000	Eichhorn et al.	
	53	6,117,160	09-12-2000	Bonutti	
	54	6,117,161	09-12-2000	Li et al.	
	55	6,126,677	10-03-2000	Ganaja et al.	
	56	6,149,669	11-21-2000	Li	
	57	6,200,330 B1	03-13-2001	Benderev et al.	
	58	6,241,749 B1	06-05-2001	Rayhanabad	

Examiner Signature	Date Considered
<p>*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>	

T<sup>1</sup> - Place a check mark in this area when an English language Translation is attached.

PTO/SB/08 Equivalent

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Multiple sheets used when necessary)</i>	Application No.	13/245622
	Filing Date	09-26-2011
	First Named Inventor	Green, Michael L. et al
	Art Unit	3773
SHEET 3 OF 8		Attorney Docket No. KFX.003C2

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	59	6,245,082 B1	06-12-2001	Gellman et al.	
	60	6,280,474 B1	08-28-2001	Cassidy et al.	
	61	6,293,961 B2	09-25-2001	Schwartz et al.	
	62	6,296,659 B1	10-02-2001	Foerster	
	63	6,306,159 B1	10-23-2001	Schwartz et al.	
	64	6,319,271 B1	11-20-2001	Schwartz et al.	
	65	6,328,758 B1	12-11-2001	Tornier et al.	
	66	6,391,030 B1	05-21-2002	Wagner et al.	
	67	6,423,065 B2	07-23-2002	Ferree	
	68	6,432,123 B1	08-13-2002	Schwartz et al.	
	69	6,464,713 B2	10-15-2002	Bonutti	
	70	6,491,714 B1	12-10-2002	Bennett	
	71	6,514,274 B1	02-04-2003	Boucher et al.	
	72	6,518,200 B2	02-11-2003	Lin	
	73	6,520,980 B1	02-18-2003	Foerster	
	74	6,524,317 B1	02-25-2003	Ritchart et al.	
	75	6,527,794 B1	03-04-2003	McDevitt et al.	
	76	6,533,795 B1	03-18-2003	Tran et al.	
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	78	6,547,800 B2	04-15-2003	Foerster et al.	
	79	6,551,330 B1	04-22-2003	Bain et al.	
	80	6,554,852 B1	04-29-2003	Oberlander	
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	86	6,635,073 B2	10-21-2003	Bonutti	
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<p>*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>	

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PTO/SB/08 Equivalent

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	Filing Date	09-26-2011
	First Named Inventor	Green, Michael L. et al
	Art Unit	3773
	Examiner	Gregory A. Anderson
SHEET 4 OF 8	Attorney Docket No.	KFX.003C2

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	88	6,641,597 B2	11-04-2003	Burkhart et al.	
	89	6,652,561 B1	11-25-2003	Tran	
	90	6,660,008 B1	12-09-2003	Foerster et al.	
	91	6,660,023 B2	12-09-2003	McDevitt et al.	
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	93	6,712,830 B2	03-30-2004	Esplin	
	94	6,770,076 B2	08-03-2004	Foerster	
	95	6,780,198 B1	08-24-2004	Gregoire et al.	
	96	6,855,157 B2	02-15-2005	Foerster et al.	
	97	6,984,241 B2	01-10-2006	Lubbers et al.	
	98	6,986,781 B2	01-17-2006	Smith	
	99	7,001,411 B1	02-21-2006	Dean	
	100	7,041,120 B2	05-09-2006	Li et al.	
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	112	7,837,710 B2	11-23-2010	Lombardo et al.	
	113	8,029,537 B2	10-04-2011	West, Jr. et al.	
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	115	2001/0008971 A1	07-19-2001	Schwartz et al.	
	116	2001/0018597 A1	08-30-2001	Gellman et al.	

Examiner Signature	Date Considered
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PTO/SB/08 Equivalent

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Multiple sheets used when necessary)</i>	Application No.	13/245622
	Filing Date	09-26-2011
	First Named Inventor	Green, Michael L. et al
	Art Unit	3773
	Examiner	Gregory A. Anderson
SHEET 5 OF 8	Attorney Docket No.	KFX.003C2

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	117	2001/0051815 A1	12-13-2001	Esplin	
	118	2001/0051816 A1	12-13-2001	Enzerink et al.	
	119	2002/0019649 A1	02-14-2002	Sikora et al.	
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	123	2002/0128684 A1	09-12-2002	Foerster	
	124	2002/0169478 A1	11-14-2002	Schwartz et al.	
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	126	2003/0018358 A1	01-23-2003	Saadat	
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	128	2003/0105591 A1	06-05-2003	Hagiwara	
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	131	2003/0181925 A1	09-25-2003	Bain et al.	
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	141	2004/0102779 A1	05-27-2004	Nesper et al.	
	142	2004/0093031 A1	05-13-2004	Burkhart et al.	
	143	2004/0116961 A1	06-17-2004	Nesper et al.	
	144	2004/0133238 A1	07-08-2004	Cerier	
	145	2004/0193217 A1	09-30-2004	Lubbers et al.	

Examiner Signature	Date Considered
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PTO/SB/08 Equivalent

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	Filing Date	09-26-2011
	First Named Inventor	Green, Michael L. et al
	Art Unit	3773
	Examiner	Gregory A. Anderson
SHEET 6 OF 8	Attorney Docket No.	KFX.003C2

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	146	2004/0225325 A1	11-11-2004	Bonutti	
	147	2004/0243178 A1	12-02-2004	Haut et al.	
	148	2004/0254609 A1	12-16-2004	Esplin	
	149	2004/0267317 A1	12-30-2004	Higgins et al.	
	150	2004/0098050 A1	05-20-2004	Foerster et al.	
	151	2005/0027307 A1	02-03-2005	Schwartz et al.	
	152	2005/0055052 A1	03-10-2005	Lombardo et al.	
	153	2005/0240199 A1	10-27-2005	Martinek et al.	
	154	2005/0240226 A1	10-27-2005	Foerster et al.	
	155	2005/0245932 A1	11-03-2005	Fanton et al.	
	156	2005/0283158 A1	12-22-2005	West	
	157	2005/0288682 A1	12-29-2005	Howe	
	158	2006/0067967 A1	03-30-2006	Bowman et al.	
	159	2006/0106423 A1	05-18-2006	Weisel et al.	
	160	2006/0116719 A1	06-01-2006	Martinek	
	161	2006/0161159 A1	07-20-2006	Dreyfuss et al.	
	162	2006/0178702 A1	08-10-2006	Pierce et al.	
	163	2006/0235413 A1	10-19-2006	Denham et al.	
	164	2006/0271060 A1	11-30-2006	Gordon	
	165	2006/0271105 A1	11-30-2006	Foerster et al.	
	166	2006/0293710 A1	12-28-2006	Foerster et al.	
	167	2007/0142835 A1	06-21-2007	Green et al.	
	168	2007/0142861 A1	06-21-2007	Burkhart	

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Cite No.	Foreign Patent Document Country Code-Number-Kind Code Example: JP 1234567 A1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T <sup>1</sup>
	169	SU 1600713	10-23-1990	Don Med Inst.		
	170	WO 1999/052478 A1	10-21-1999	Axya Medical, Inc.		

Examiner Signature	Date Considered
<b>*Examiner:</b> Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

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PTO/SB/08 Equivalent

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Multiple sheets used when necessary)</i>  <b>SHEET 7 OF 8</b>	Application No.	13/245622
	Filing Date	09-26-2011
	First Named Inventor	Green, Michael L. et al
	Art Unit	3773
	Examiner	Gregory A. Anderson
	Attorney Docket No.	KFX.003C2

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Cite No.	Foreign Patent Document Country Code-Number-Kind Code Example: JP 1234567 A1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T <sup>1</sup>
	171	WO 2001/054586 A1	08-02-2001	Shoulderon Ltd.		
	172	WO 2001/067962 A2	09-20-2001	Rosch		
	173	WO 2002/011630 A1	02-14-2002	The Cleveland Clinic Foundation		
	174	WO 2002/021998 A1	03-31-2002	Axya Medical Inc.		
	175	WO 2003/065904 A1	08-14-2003	Opus Medical, Inc.		
	176	WO 2004/062506 A1	07-29-2004	Linvatec Biomaterials OY		
	177	WO 2005/112786 A2	12-01-2005	Ethicon Endo-Surgery, Inc.		
	178	WO 2005/112788 A2	12-01-2005	Arthrocare Corporation		
	179	WO 2006/060035 A2	06-08-2006	3I Medical Corporation		
	180	WO 2006/067548 A1	06-29-2006	Arthrex, Inc.		
	181	WO 2006/128092 A2	11-30-2006	Arthrocare Corporation		
	182	WO 2007/084714 A2	07-26-2007	Kim		

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>1</sup>
	183	Arthrex, Inc.'s Answer to Plaintiff KFX Medical Corp.'s complaint For Patent Infringement and Counterclaims, United States District Court , Southern District of California, September 23, 2011, Los Angeles, USA.	
	184	Complaint for Patent Infringement, dated August 1, 2011, KFX Medical Corporation v. Arthrex, Inc., (S.D.C.A.).	
	185	International Preliminary Report on Patentability dated January 25, 2007 for International Application No. PCT/US2005/019454.	
	186	International Search Report and Written Opinion of the International Searching Authority, dated September 6, 2006, for International Application No. PCT/US2005/019454.	
	187	LO et al., "Double-Row Arthroscopic Rotator Cuff Repair: Re-Establishing the Footprint of the Rotator Cuff, Arthroscopy: The Journal of Arthroscopic and Related Surgery, November, 2003, pgs. 1035-1042, Vol. 19, No. 9.	
	188	MAZZOCCA et al., Arthroscopic Single-Row Versus Double-Row Suture Anchor Rotator Cuff Repair," The American Journal of Sports Medicine, 2005, 33:1861.	
	189	MAZZOCCA et al., Arthroscopic Single versus Double Row Suture Anchor Rotator Cuff Repair, abstract of presentation made on June 25, 2004 at 2004 Annual Meeting of the American Orthopaedic Society for Sports Medicine in Quebec, Canada, publication date unknown.	
	190	MILLETT et al., Mattress double anchor footprint repair: a novel, arthroscopic rotator cuff repair technique, Arthroscopy: The Journal of Arthroscopic and Related Surgery, 20(8):875-879 (2004).	

Examiner Signature	Date Considered
<p>*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>	

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	Filing Date	09-26-2011
	First Named Inventor	Green, Michael L. et al
	Art Unit	3773
	Examiner	Gregory A. Anderson
SHEET 8 OF 8	Attorney Docket No.	KFX.003C2

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>1</sup>
	191	PAULOS, M.D., Graftjacket Regenerative Tissue Matrix Rotator Cuff, date unknown, Wright Medical Technology, Inc.; Wright Cremascoli Ortho SA.	
	192	PCT International Preliminary Report on Patentability, dated May 22, 2009, for International Application No. PCT/US2007/083662.	
	193	PCT International Search Report and Written Opinion, dated August 8, 2008, for International Application No. PCT/US2007/083662.	
	194	PCT Invitation to Pay Additional Fees, dated May 13, 2008, for International Application No. PCT/US2007/083662.	
	195	ROBBE, M.D. et al., Knotless Suture-based Anchors, Operative Techniques in Sports Medicine, 2004, pgs. 221-224, Elsevier Inc.	
	196	SELDES, M.D., et al., Tissue Mend Arthroscopic Insertion of a Biologic Rotator Cuff Tissue Augment After Rotator Cuff Repair, Stryker, date unknown, pgs. 1-7.	
	197	Statement of Tate Scott, dated April 12, 2011, submitted in Re-Examination No. 90/011,430.	
	198	TissueMend Advanced Soft Tissue Repair Matrix, Stryker, date unknown.	
	199	TissueMend Soft Tissue Repair Matrix, Stryker, 2004, USA.	
	200	WALTRIP, "Rotator Cuff Repair A Biomechanical Comparison of Three Techniques", The American Journal of Sports Medicine, 2003, pgs. 493-497, No. 4.	
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Examiner Signature	Date Considered
<p>*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>	

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# **EXHIBIT 6**

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	13/245,620	GREEN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	GREGORY ANDERSON	3773	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to communications received up to 26 September 2011.
2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on \_\_\_\_; the restriction requirement and election have been incorporated into this action.
3. ☒ The allowed claim(s) is/are 1-19.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
  1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS ( "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_.

**Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

<b>Attachment(s)</b>	
1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date <u>12012011</u> 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material	5. <input type="checkbox"/> Notice of Informal Patent Application 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413), Paper No./Mail Date <u>20111202</u> . 7. <input type="checkbox"/> Examiner's Amendment/Comment 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance 9. <input type="checkbox"/> Other ____

/GREGORY ANDERSON/ Examiner, Art Unit 3773	/Darwin P. Erez/ Primary Examiner, Art Unit 3773
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Application/Control Number: 13/245,620  
Art Unit: 3773

Page 2

## **DETAILED ACTION**

### ***Terminal Disclaimer***

1. The terminal disclaimer filed on 05 December 2011 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Patent No. 7,585,311 has been reviewed and is accepted. The terminal disclaimer has been recorded.

### ***Reasons for Allowance***

2. Claims 1-19 are allowed.

3. The following is an examiner's statement of reasons for allowance: Thal 5,569,306 discloses a method of attaching soft tissue to bone comprising: inserting a first anchor 26 into bone 28, wherein the first anchor is positioned underneath the soft tissue 30; passing a first length of suture 42 from said first anchor over the soft tissue; inserting a second anchor 24 into bone, wherein the second anchor is positioned laterally to the soft tissue; and fixedly securing the first length of suture to the second anchor without tying any knots (Fig. 2). Jobe 5,634,926 discloses anchors being positioned beyond an edge of the soft tissue such that it is not underneath the soft tissue (Fig. 9, Col. 8 ll. 34-37). However, neither Thal nor Jobe disclose after inserting the second anchor, tensioning the first length of suture to compress an area of tissue to bone between the edge of the soft tissue and the first anchor. The prior art of record nor the prior art at large, alone or in combination, cannot remedy the deficiencies of the Thal and Jobe references and thus the claims are allowed.

Application/Control Number: 13/245,620  
Art Unit: 3773

Page 3

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

***Conclusion***

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory A Anderson whose telephone number is (571)270-3083. The examiner can normally be reached on Mon-Thurs 9:30am-3pm EST.

If attempts to reach the examiner by telephone are unsuccessful, ***please contact the examiner's supervisor, Corrine McDermott, at (571) 272-4754.*** The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

***If there are any inquiries that are not being addressed by first contacting the Examiner or the Supervisor, you may send an email inquiry to TC3700\_Workgroup\_D\_Inquiries@uspto.gov.***

Application/Control Number: 13/245,620  
Art Unit: 3773

Page 4

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/GREGORY ANDERSON/  
Examiner, Art Unit 3773

/Darwin P. Erez/  
Primary Examiner, Art Unit 3773

# **EXHIBIT 7**

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	13/245,622	GREEN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	GREGORY ANDERSON	3773	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to communications filed up to 26 September 2011.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on \_\_\_\_; the restriction requirement and election have been incorporated into this action.

3. ☒ The allowed claim(s) is/are 1-17.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.

3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.

(a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached

1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_.

(b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_.

**Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date <u>12012011</u> 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material	5. <input type="checkbox"/> Notice of Informal Patent Application 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413), Paper No./Mail Date <u>20111202</u> 7. <input type="checkbox"/> Examiner's Amendment/Comment 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance 9. <input type="checkbox"/> Other ____
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/GREGORY ANDERSON/ Examiner, Art Unit 3773	/Darwin P. Erez/ Primary Examiner, Art Unit 3773
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Application/Control Number: 13/245,622  
Art Unit: 3773

Page 2

## **DETAILED ACTION**

### ***Terminal Disclaimer***

1. The terminal disclaimer filed on 05 December 2011 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Patent No. 7,585,311 has been reviewed and is accepted. The terminal disclaimer has been recorded.

### ***Reasons for Allowance***

2. Claims 1-17 are allowed.

3. The following is an examiner's statement of reasons for allowance: Thal 5,569,306 discloses a method of attaching soft tissue to bone comprising: inserting a first anchor 26 into bone 28, wherein the first anchor is positioned underneath the soft tissue 30; passing a first length of suture 42 from said first anchor over the soft tissue; inserting a second anchor 24 into bone, wherein the second anchor is positioned laterally to the soft tissue; and fixedly securing the first length of suture to the second anchor without tying any knots (Fig. 2). Jobe 5,634,926 discloses anchors being positioned beyond an edge of the soft tissue such that it is not underneath the soft tissue (Fig. 9, Col. 8 ll. 34-37). However, neither Thal nor Jobe disclose after inserting the second anchor, tensioning the first length of suture to compress an area of tissue to bone between the edge of the soft tissue and the first anchor. The prior art of record nor the prior art at large, alone or in combination, cannot remedy the deficiencies of the Thal and Jobe references and thus the claims are allowed.



Application/Control Number: 13/245,622  
Art Unit: 3773

Page 3

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

***Conclusion***

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory A Anderson whose telephone number is (571)270-3083. The examiner can normally be reached on Mon-Thurs 9:30am-3pm EST.

If attempts to reach the examiner by telephone are unsuccessful, ***please contact the examiner's supervisor, Corrine McDermott, at (571) 272-4754.*** The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

***If there are any inquiries that are not being addressed by first contacting the Examiner or the Supervisor, you may send an email inquiry to***

***TC3700\_Workgroup\_D\_Inquiries@uspto.gov.***

Application/Control Number: 13/245,622  
Art Unit: 3773

Page 4

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/GREGORY ANDERSON/  
Examiner, Art Unit 3773

/Darwin P. Erez/  
Primary Examiner, Art Unit 3773

# **EXHIBIT 8**

Receipt date: 12/01/2011

13245620 - GAU: 3773

PTO/SB/08 Equivalent

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>	Application No.	13/245620
	Filing Date	09-26-2011
	First Named Inventor	Green, Michael L. et al
	Art Unit	3773
(Multiple sheets used when necessary)	Examiner	Gregory A. Anderson
SHEET 1 OF 8	Attorney Docket No.	KFX.003C1

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	1	3,623,192	11-30-1971	Button	
	2	4,210,148	07-01-1980	Stivala	
	3	4,532,926	08-06-1985	O'Holla	
	4	4,796,612	01-10-1989	Reese	
	5	4,898,156	02-06-1990	Gattorna et al.	
	6	5,013,316	05-07-1991	Goble et al.	
	7	5,192,303	03-09-1993	Gattorna et al.	
	8	5,219,359	06-15-1993	McQuilkin et al.	
	9	5,224,946	07-06-1993	Hayhurst et al.	
	10	5,269,784	12-14-1993	Mast	
	11	5,336,240	08-09-1994	Metzler et al.	
	12	5,372,604	12-13-1994	Trott	
	13	5,417,712	05-23-1995	Whittaker et al.	
	14	5,423,858	06-13-1995	Bolanos et al.	
	15	5,423,860	06-13-1995	Lizardi et al.	
	16	5,472,452	12-05-1995	Trott	
	17	5,478,353	12-26-1995	Yoon	
	18	5,500,001	03-19-1996	Trott	
	19	5,527,341	06-18-1996	Gogolewski et al.	
	20	5,527,343	06-18-1996	Bonutti	
	21	5,543,012	08-06-1996	Watson et al.	
	22	5,545,180	08-13-1996	Le et al.	
	23	5,569,306	10-29-1996	Thal	
	24	5,575,801	11-19-1996	Habermeyer et al.	
	25	5,578,057	11-26-1996	Wenstrom, Jr.	
	26	5,584,835	12-17-1996	Greenfield	
	27	5,591,207	01-07-1997	Coleman	
	28	5,634,926	06-03-1997	Jobe	
	29	5,683,419	11-04-1997	Thal	

Examiner Signature /Gregory Anderson/	Date Considered 12/02/2011
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

Place a check mark in this area when an English language Translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.A./

Receipt date: 12/01/2011

13245620 - GAU: 3773

PTO/SB/08 Equivalent

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Multiple sheets used when necessary)</i>  SHEET 2 OF 8	Application No.	13/245620
	Filing Date	09-26-2011
	First Named Inventor	Green, Michael L. et al
	Art Unit	3773
	Examiner	Gregory A. Anderson
	Attorney Docket No.	KFX.003C1

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	30	5,690,676	11-25-1997	DiPoto et al.	
	31	5,697,950	12-16-1997	Fucci et al.	
	32	5,720,765	02-24-1998	Thal	
	33	5,725,557	03-10-1998	Gattuma	
	34	5,769,894	06-23-1998	Ferragamo	
	35	5,800,436	09-01-1998	Lerch	
	36	5,814,072	09-29-1998	Bonutti	
	37	5,891,168	04-06-1999	Thal	
	38	5,948,001	09-07-1999	Larsen	
	39	5,948,002	09-07-1999	Bonutti	
	40	5,951,590	09-14-1999	Goldfarb	
	41	5,964,769	10-12-1999	Wagner et al.	
	42	6,010,525	01-04-2000	Bonutti et al.	
	43	6,013,077	01-11-2000	Harwin	
	44	6,013,083	01-11-2000	Bennett	
	45	6,027,523	02-22-2000	Schmieding	
	46	6,045,573	04-04-2000	Wenstrom, Jr. et al.	
	47	6,056,751	05-02-2000	Fenton, Jr.	
	48	6,063,106	05-16-2000	Gibson	
	49	6,093,201	07-25-2000	Cooper et al.	
	50	6,093,301	07-25-2000	Van Atta	
	51	6,099,547	08-08-2000	Gellman et al.	
	52	6,110,207	08-29-2000	Eichhorn et al.	
	53	6,117,160	09-12-2000	Bonutti	
	54	6,117,161	09-12-2000	Li et al.	
	55	6,126,677	10-03-2000	Ganaja et al.	
	56	6,149,669	11-21-2000	Li	
	57	6,200,330 B1	03-13-2001	Benderev et al.	
	58	6,241,749 B1	06-05-2001	Rayhanabad	

Examiner Signature	/Gregory Anderson/	Date Considered	12/02/2011
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.			

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EXHIBIT 8

PAGE 136

Receipt date: 12/01/2011

13245620 - GAU: 3773

PTO/SB/08 Equivalent

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>	Application No.	13/245620
	Filing Date	09-26-2011
	First Named Inventor	Green, Michael L. et al
	Art Unit	3773
(Multiple sheets used when necessary)	Examiner	Gregory A. Anderson
SHEET 3 OF 8	Attorney Docket No.	KFX.003C1

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	59	6,245,082 B1	06-12-2001	Gellman et al.	
	60	6,280,474 B1	08-28-2001	Cassidy et al.	
	61	6,293,961 B2	09-25-2001	Schwartz et al.	
	62	6,296,659 B1	10-02-2001	Foerster	
	63	6,306,159 B1	10-23-2001	Schwartz et al.	
	64	6,319,271 B1	11-20-2001	Schwartz et al.	
	65	6,328,758 B1	12-11-2001	Tornier et al.	
	66	6,391,030 B1	05-21-2002	Wagner et al.	
	67	6,423,065 B2	07-23-2002	Ferree	
	68	6,432,123 B1	08-13-2002	Schwartz et al.	
	69	6,464,713 B2	10-15-2002	Bonutti	
	70	6,491,714 B1	12-10-2002	Bennett	
	71	6,514,274 B1	02-04-2003	Boucher et al.	
	72	6,518,200 B2	02-11-2003	Lin	
	73	6,520,980 B1	02-18-2003	Foerster	
	74	6,524,317 B1	02-25-2003	Ritchart et al.	
	75	6,527,794 B1	03-04-2003	McDevitt et al.	
	76	6,533,795 B1	03-18-2003	Tran et al.	
	77	6,540,770 B1	04-01-2003	Tornier et al.	
	78	6,547,800 B2	04-15-2003	Foerster et al.	
	79	6,551,330 B1	04-22-2003	Bain et al.	
	80	6,554,852 B1	04-29-2003	Oberländer	
	81	6,569,187 B1	05-27-2003	Bonutti et al.	
	82	6,575,987 B2	06-10-2003	Gellman et al.	
	83	6,582,453 B1	06-24-2003	Tran et al.	
	84	6,585,730 B1	07-01-2003	Foerster	
	85	6,605,096 B1	08-12-2003	Ritchart	
	86	6,635,073 B2	10-21-2003	Bonutti	
	87	6,638,279 B2	10-28-2003	Bonutti	

Examiner Signature	/Gregory Anderson/	Date Considered	12/02/2011
<p>*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>			

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EXHIBIT 8

PAGE 137

Receipt date: 12/01/2011

13245620 - GAU: 3773

PTO/SB/08 Equivalent

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Multiple sheets used when necessary)</i>  SHEET 4 OF 8	Application No.	13/245620
	Filing Date	09-26-2011
	First Named Inventor	Green, Michael L. et al
	Art Unit	3773
	Examiner	Gregory A. Anderson
	Attorney Docket No.	KFX.003C1

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	88	6,641,597 B2	11-04-2003	Burkhart et al.	
	89	6,652,561 B1	11-25-2003	Tran	
	90	6,660,008 B1	12-09-2003	Foerster et al.	
	91	6,660,023 B2	12-09-2003	McDevitt et al.	
	92	6,673,094 B1	01-06-2004	McDevitt et al.	
	93	6,712,830 B2	03-30-2004	Esplin	
	94	6,770,076 B2	08-03-2004	Foerster	
	95	6,780,198 B1	08-24-2004	Gregoire et al.	
	96	6,855,157 B2	02-15-2005	Foerster et al.	
	97	6,984,241 B2	01-10-2006	Lubbers et al.	
	98	6,986,781 B2	01-17-2006	Smith	
	99	7,001,411 B1	02-21-2006	Dean	
	100	7,041,120 B2	05-09-2006	Li et al.	
	101	7,056,333 B2	06-06-2006	Walshe	
	102	7,081,126 B2	07-25-2006	McDevitt et al.	
	103	7,083,638 B2	08-01-2006	Foerster	
	104	7,090,690 B2	08-15-2006	Foerster et al.	
	105	7,144,415 B2	12-05-2006	Del Rio et al.	
	106	7,153,312 B1	12-26-2006	Torrie et al.	
	107	7,156,864 B2	01-02-2007	Lintner	
	108	7,232,455 B2	06-19-2007	Pedlick et al.	
	109	7,235,100 B2	06-26-2007	Martinek	
	110	7,247,164 B1	07-24-2007	Ritchart et al.	
	111	7,517,357 B2	04-14-2009	Abrams et al.	
	112	7,837,710 B2	11-23-2010	Lombardo et al.	
	113	8,029,537 B2	10-04-2011	West, Jr. et al.	
	114	RE 36,289	08-31-1999	Le et al.	
	115	2001/0008971 A1	07-19-2001	Schwartz et al.	
	116	2001/0018597 A1	08-30-2001	Gellman et al.	

Examiner Signature	/Gregory Anderson/	Date Considered	12/02/2011
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.			

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EXHIBIT 8

PAGE 138



Receipt date: 12/01/2011

13245620 - GAU: 3773

PTO/SB/08 Equivalent

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>	Application No.	13/245620
	Filing Date	09-26-2011
	First Named Inventor	Green, Michael L. et al
	Art Unit	3773
(Multiple sheets used when necessary)	Examiner	Gregory A. Anderson
SHEET 5 OF 8	Attorney Docket No.	KFX.003C1

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	117	2001/0051815 A1	12-13-2001	Esplin	
	118	2001/0051816 A1	12-13-2001	Enzerink et al.	
	119	2002/0019649 A1	02-14-2002	Sikora et al.	
	120	2002/0029066 A1	03-07-2002	Foerster	
	121	2002/0077631 A1	06-20-2002	Lubbers et al.	
	122	2002/0111653 A1	08-15-2002	Foerster	
	123	2002/0128684 A1	09-12-2002	Foerster	
	124	2002/0169478 A1	11-14-2002	Schwartz et al.	
	125	2002/0188305 A1	12-12-2003	Foerster et al.	
	126	2003/0018358 A1	01-23-2003	Saadat	
	127	2003/0088270 A1	05-08-2003	Lubbers et al.	
	128	2003/0105591 A1	06-05-2003	Hagiwara	
	129	2003/0149448 A1	08-07-2003	Foerster et al.	
	130	2003/0167072 A1	09-04-2003	Oberlander	
	131	2003/0181925 A1	09-25-2003	Bain et al.	
	132	2003/0191498 A1	10-09-2003	Foerster et al.	
	133	2003/0195528 A1	10-16-2003	Ritchart	
	134	2003/0195563 A1	10-16-2003	Foerster	
	135	2003/0195564 A1	10-16-2003	Tran et al.	
	136	2003/0204204 A1	10-30-2003	Bonutti	
	137	2003/0236555 A1	12-25-2003	Thornes	
	138	2004/0002735 A1	01-01-2004	Lizardi et al.	
	139	2004/0024420 A1	02-05-2004	Lubbers et al.	
	140	2004/0044366 A1	03-04-2004	Bonutti et al.	
	141	2004/0102779 A1	05-27-2004	Nesper et al.	
	142	2004/0093031 A1	05-13-2004	Burkhart et al.	
	143	2004/0116961 A1	06-17-2004	Nesper et al.	
	144	2004/0133238 A1	07-08-2004	Cerier	
	145	2004/0193217 A1	09-30-2004	Lubbers et al.	

Examiner Signature	/Gregory Anderson/	Date Considered	12/02/2011
<p>*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>			

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Receipt date: 12/01/2011

13245620 - GAU: 3773

PTO/SB/08 Equivalent

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>	Application No.	13/245620
	Filing Date	09-26-2011
	First Named Inventor	Green, Michael L. et al
	Art Unit	3773
(Multiple sheets used when necessary)	Examiner	Gregory A. Anderson
SHEET 6 OF 8	Attorney Docket No.	KFX.003C1

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	146	2004/0225325 A1	11-11-2004	Bonutti	
	147	2004/0243178 A1	12-02-2004	Haut et al.	
	148	2004/0254609 A1	12-16-2004	Esplin	
	149	2004/0267317 A1	12-30-2004	Higgins et al.	
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	169	SU 1600713	10-23-1990	Don Med Inst.		
	170	WO 1999/052478 A1	10-21-1999	Axya Medical, Inc.		

Examiner Signature /Gregory Anderson/	Date Considered 12/02/2011
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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.A./

Receipt date: 12/01/2011

13245620 - GAU: 3773

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Multiple sheets used when necessary)</i>  SHEET 7 OF 8	Application No.	13/245620
	Filing Date	09-26-2011
	First Named Inventor	Green, Michael L. et al
	Art Unit	3773
	Examiner	Gregory A. Anderson
	Attorney Docket No.	KFX.003C1

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Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>1</sup>	
	183	Arthrex, Inc.'s Answer to Plaintiff KFX Medical Corp.'s complaint For Patent Infringement and Counterclaims, United States District Court , Southern District of California, September 23, 2011, Los Angeles, USA.		
	184	Complaint for Patent Infringement, dated August 1, 2011, KFX Medical Corporation v. Arthrex; Inc., (S.D.C.A.).		
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	Art Unit	3773
(Multiple sheets used when necessary)	Examiner	Gregory A. Anderson
SHEET 8 OF 8	Attorney Docket No.	KFX.003C1

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# **EXHIBIT 9**

Receipt date: 12/01/2011

13245622 - GAU: 3773

PTO/SB/08 Equivalent

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Multiple sheets used when necessary)</i> <b>SHEET 2 OF 8</b>	Application No.	13/245622
	Filing Date	09-26-2011
	First Named Inventor	Green, Michael L. et al
	Art Unit	3773
	Examiner	Gregory A. Anderson
	Attorney Docket No.	KFX.003C2

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
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13245622 - GAU: 3773

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>	Application No.	13/245622
	Filing Date	09-26-2011
	First Named Inventor	Green, Michael L. et al
	Art Unit	3773
(Multiple sheets used when necessary)	Examiner	Gregory A. Anderson
SHEET 3 OF 8	Attorney Docket No.	KFX.003C2

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
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13245622 - GAU: 3773

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Multiple sheets used when necessary)</i> <b>SHEET 4 OF 8</b>	Application No.	13/245622
	Filing Date	09-26-2011
	First Named Inventor	Green, Michael L. et al
	Art Unit	3773
	Examiner	Gregory A. Anderson
	Attorney Docket No.	KFX.003C2

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13245622 - GAU: 3773

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Multiple sheets used when necessary)</i>	Application No.	13/245622
	Filing Date	09-26-2011
	First Named Inventor	Green, Michael L. et al
	Art Unit	3773
	Examiner	Gregory A. Anderson
SHEET 5 OF 8	Attorney Docket No.	KFX.003C2

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	Filing Date	09-26-2011
	First Named Inventor	Green, Michael L. et al
	Art Unit	3773
SHEET 6 OF 8		Examiner Gregory A. Anderson
		Attorney Docket No. KFX.003C2

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	170	WO 1999/052478 A1	10-21-1999	Axya Medical, Inc.		

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SHEET 7 OF 8	Attorney Docket No.	KFX.003C2

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Examiner Initials	Cite No.	Foreign Patent Document Country Code-Number-Kind Code Example: JP 1234567 A1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T <sup>1</sup>
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	182	WO 2007/084714 A2	07-26-2007	Kim		

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>1</sup>
	183	Arthrex, Inc.'s Answer to Plaintiff KFX Medical Corp.'s complaint For Patent Infringement and Counterclaims, United States District Court , Southern District of California, September 23, 2011, Los Angeles, USA.	
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Examiner Signature /Gregory Anderson/	Date Considered 12/13/2011
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

T<sup>1</sup> - Place a check mark in this area when an English language Translation is attached.  
 ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.A./

Receipt date: 12/01/2011

13245622 - GAU: 3773

PTO/SB/08 Equivalent

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Multiple sheets used when necessary)</i>  SHEET 8 OF 8	Application No.	13/245622
	Filing Date	09-26-2011
	First Named Inventor	Green, Michael L. et al
	Art Unit	3773
	Examiner	Gregory A. Anderson
	Attorney Docket No.	KFX.003C2

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>1</sup>
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Examiner Signature	/Gregory Anderson/	Date Considered	12/13/2011
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.			

T<sup>1</sup> - Place a check mark in this area when an English language Translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.A./

# **EXHIBIT 10**

Docket No.: **KFX.003C2**

**Customer No. 20995**

**INFORMATION DISCLOSURE STATEMENT**

Applicant	:	Michael L. Green, et al.
App. No.	:	13/245622
Filed	:	September 26, 2011
For	:	SYSTEM AND METHOD FOR ATTACHING SOFT TISSUE TO BONE
Examiner	:	Gregory A. Anderson
Art Unit	:	3773
Conf. No.	:	8012

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**References and Listing**

Submitted herewith in the above-identified application is an Information Disclosure Statement listing references for consideration. Copies of any listed foreign and non-patent literature references are being submitted.

**Timing of Disclosure**

This Information Disclosure Statement is being filed after the mailing date of a final action or after the mailing date of a Notice of Allowance. Please place these references in the file in accordance with 37 CFR 1.97(i).

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 2-6-12

By: Ryan Melnick  
Ryan E. Melnick  
Registration No. 58,621  
Attorney of Record  
Customer No. 20995  
(858) 707-4000

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PTO/SB/08 Equivalent

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Multiple sheets used when necessary)</i>	Application No.	13/245622
	Filing Date	September 26, 2011
	First Named Inventor	Michael L. Green et al.
	Art Unit	3773
SHEET 1 OF 1		Attorney Docket No. KFX.003C2

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
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FOREIGN PATENT DOCUMENTS						
Examiner Initials	Cite No.	Foreign Patent Document Country Code-Number-Kind Code Example: JP 1234567 A1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T <sup>1</sup>

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>1</sup>
	12	ARTHREX, INC., Defendant and Counterclaimant Arthrex, Inc.'s Preliminary Invalidation Contentions (including Appendix 1-4) filed in the United States District Court Southern District of California on January 30, 2012.	
	13	ARTHREX, INC., Scope This Out, A Technical Pearls Newsletter for Arthroscopists, 2003, pgs. 1-4, Vol. 5, Number 3, Arthrex, Inc., USA.	
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Examiner Signature	Date Considered
<b>*Examiner:</b> Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

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